

REMARKS

The Office Action of October 7, 2008, has been carefully reviewed, and in view of the above amendments and the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

As has been discussed in some detail in previous communications, the primary reference upon which the Examiner relies, *Huston et al.* (U.S. Patent No. 3,407,027)(hereinafter *Huston*) discloses an autoclave chamber comprising a relatively thin inner shell 14 made of a high quality corrosion resistant material, and an outer shell 12 which is typically not corrosion resistant. The structural strength required for the pressure autoclave chamber taught by *Huston* is provided by the outer shell 12 (col. 2, lines 21-24) which supports the inner shell 14 via the stay bars 28, that are arranged between the shells to transfer force from the inner shell 14 to the outer shell 12 (col. 1, lines 27-33; col. 2, lines 5-7; Fig 2). Accordingly, the inner shell 14 alone cannot be considered to be a self-supported pressure chamber for use in an autoclave, and the only self-supported pressure chamber disclosed by Huston is the sandwich construction formed by the inner shell 14, the outer shell 12 and the stay bars 28.

The Examiner further refers to *Hennebert et al.* (U.S. Patent No. 4,764,351)(hereinafter *Hennebert*) which discloses a sterilization apparatus for sterilization of temperature sensitive objects using biocidal gases, such as ethylene oxide or formaldehyde. According to one embodiment, the sterilization apparatus taught by *Hennebert* comprises a plastic chamber. *Hennebert* teaches (col. 5, lines 22-27) that the plastic chamber withstands the forces due to subatmospheric pressures.

In contrast to the sterilization apparatus according to *Hennebert*, an autoclave device for steam sterilization uses high temperature and pressure to ensure that the objects to be sterilized are properly sterilized. Furthermore, the sterilization cycle to be used by an autoclave device is rigorously specified and involves subjecting the objects to be sterilized to pressures ranging between from near absolute vacuum to at least around 2.2 bar. That the pressure necessarily has to reach at least 2.2 bar is clear from the enclosed copy of "European Standard EN 13060", June 2004, Table 3 (page 23), which gives the required temperature (at least 121°C) and Equation (1) (page 11) for conversion between temperature and pressure. The corresponding U.S. standard is the ANSI/AAMI ST 55:2003.

On the contrary, the pressures used in the sterilization process taught by *Hennebert* range from around 0.1 bar to 1 bar (Fig. 6). It must therefore be assumed that the plastic chamber disclosed by *Hennebert* is configured to withstand the forces resulting from the pressure range taught by *Hennebert*, and not to withstand the considerably larger forces involved in steam sterilization.

Accordingly, the person of ordinary skill in the art of sterilization would immediately realize that the plastic chamber taught by *Hennebert* is not a self-supporting pressure chamber of the kind that could be used in an autoclave device, which means that there would be no motivation for the person of ordinary skill in the art to try to combine the teachings of *Hennebert* with those of *Huston*.

Furthermore, assuming merely for the sake of argument that the skilled person would try to combine *Huston* and *Hennebert*, he would not end up with the autoclave device according to the present invention as defined by the newly added independent claim 28, for at least the reasons discussed below:

I. The outer shell 12 is considered to be the housing of the autoclave chamber according to *Huston*.

If the outer shell 12 of the autoclave device according to *Huston* is considered to be a "housing", then the inner shell 14 would be the chamber for enclosing goods to be sterilized.

Based on this interpretation, the difference between the autoclave device according to the claimed invention and that taught by *Huston* would be:

- 1) that the chamber is a *self-supported* pressure chamber (the inner shell 14 is not self-supported, but needs the support of the structurally stronger outer shell 12 to withstand the pressure formed when the autoclave device is in operation);
- 2) that the chamber is manufactured from a polymer material; and
- 3) that the chamber comprises polymer fastening portions at which the pressure chamber is attached to the housing.

As mentioned above, there would be no motivation for the skilled person to combine the teachings of *Huston* with those of *Hennebert*. If it were to be assumed, merely for the sake of argument, that the person of ordinary skill would try to somehow replace the inner shell 14 of the autoclave chamber according to *Huston* with the plastic chamber taught by *Hennebert*, he would end up with a sandwich construction having an inner shell made of plastic. However, the chamber (the inner shell) would still not be a *self-supported* pressure chamber, and there would be no polymer fastening portions at which the chamber would be attached to the housing. Hence, the device resulting from the combination of *Huston* and *Hennebert* would not have all the features of the autoclave device according to the claimed invention.

II. The sandwich construction comprising the inner shell 14, the outer shell 12 and the stay bars 28 is considered to form a self-supported pressure chamber for enclosing goods to be sterilized.

Based on this interpretation, the difference between the autoclave device according to the claimed invention and that taught by *Huston* would be:

- 1) that the autoclave device has a housing;
- 2) that the chamber is manufactured from a polymer material; and
- 3) that the chamber comprises polymer fastening portions at which the pressure chamber is attached to the housing.

As mentioned above, there would be no motivation for the skilled person to combine the teachings of *Huston* with those of *Hennebert*. If it were to be assumed, merely for the sake of argument, that the person of ordinary skill would try to somehow replace the self-supported pressure chamber (namely the sandwich construction comprising the inner shell 14, the outer shell 12 and the stay bars 28 according to *Huston* with the plastic chamber taught by *Hennebert*, he would end up with a plastic chamber, which would not be configured for the forces developed during a steam sterilization cycle. In other words, the skilled person would end up with a device that would simply not work for the intended purpose. Furthermore, the device would lack a housing and the chamber would not be a *self-supported* pressure chamber, and would not have polymer fastening portions. Hence, the device resulting from the combination of *Huston* and *Hennebert* would not have all the features of the autoclave device according to the present invention.

In conclusion, there is nothing that would motivate the skilled person to combine the teachings of *Huston* with those of *Hennebert*, and even if he would try

to do so, the skilled person would not arrive at the autoclave device as defined by the newly added independent claim 28.

The additional references relied upon by the Examiner in the previous Office Action do not overcome the teaching found to be lacking in *Huston* and *Hennebert*. Accordingly, Applicant respectfully submits that the invention defined by the newly added independent claim is both novel and non-obvious over the cited art.

The remaining dependent claims define further distinguishing features associated with the claimed invention. Applicant makes no admissions regarding the Examiner's assertions relating to the dependent claims. These dependent claims are allowable at least by virtue of their dependence from allowable independent claim 28. Thus, a detailed discussion of the additional distinguishing features recited in these dependent claims is not set forth at this time.

CONCLUSION

In view of the above amendments and remarks, Applicant respectfully submits that the claims of the present application are now in condition for allowance, and an early indication of the same is earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference would be helpful in resolving any remaining issues pertaining to this application; the Examiner is kindly invited to call the undersigned counsel for Applicant regarding the same.

Respectfully submitted,

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Date: April 7, 2009

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English version

Small steam sterilizers

Petits stérilisateurs à la vapeur d'eau

Dampf-Klein-Sterilisatoren

This European Standard was approved by CEN on 16 April 2004.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Foreword

This document (EN 13060:2004) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA which is an integral part of this document.

The annexes A, B, C, D, E and F are informative.

This document includes a Bibliography.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

Small steam sterilizers are widely used for medical purposes, e.g. in general medical practices, dentistry, facilities for personal hygiene and beauty care and also veterinary practices. They are also used for materials and equipment, which are likely to come into contact with blood or body fluids, e.g. implements used by beauty therapists, tattooists, body piercers and hairdressers. The very specific sterilizer loads used within these fields of application call for different performance requirements for the sterilization cycles and different corresponding test methods.

This European Standard specifies the general requirements for small steam sterilizers and test methods for specified sterilizer loads according to Table 1. These loads include unwrapped solid products, full porous load, small porous load, small porous items, hollow loads A, hollow loads B, single wrapped products and double wrapped products. The performance tests specified in this standard can also be used by device manufacturers to specify the appropriate performance for decontamination processes according to the requirements for information to be given by medical device manufacturers according to EN ISO 17664:2004. This will enable users to identify the specific sterilizer performance required to safely process their devices.

Table 1 — Types of sterilization cycles

Type	Description of intended use
B	The sterilization of all wrapped or non-wrapped, solid, hollow load products type A and porous products as represented by the test loads in this standard.
N	The sterilization of non wrapped solid products.
S	The sterilization of products as specified by the manufacturer of the sterilizer including non wrapped solid products and at least one of the following: porous products, small porous items, hollow load products type A, hollow load products B, single wrapped products, multiple-layer wrapped products.
NOTE 1 The description identifies ranges of products and test loads.	
NOTE 2 Non wrapped sterilized instruments are intended either for immediate use or for non sterile storage, transport and application (e.g. to prevent cross infection).	

It is essential that the sterilizer and associated equipment is used only for the sterilization of the type of products for which it is designed. The choice of sterilizer, sterilization cycle or quality of services provided can be inappropriate for a particular load. Therefore the suitability of a sterilization procedure for a particular product needs to be verified by validation.

1 Scope

This European Standard specifies the performance requirements and test methods for small steam sterilizers and sterilization cycles which are used for medical purposes or for materials that are likely to come into contact with blood or body fluids.

This European Standard applies to automatically controlled small steam sterilizers that generate steam using electrical heaters or use steam that is generated by a system external to the sterilizer.

This European Standard applies to small steam sterilizers used primarily for the sterilization of medical devices and unable to accommodate a sterilization module (300 mm × 300 mm × 600 mm) and with a chamber volume not exceeding 60 litres.

This European Standard does not apply to small steam sterilizers that are used to sterilize liquids or pharmaceutical products.

This European Standard does not specify safety requirements related to risks associated with the zone in which the sterilizer is used (e.g. flammable gases).

This European Standard does not specify requirements for the validation and routine control of sterilization by moist heat.

NOTE Requirements for the validation and routine control of sterilization by moist heat are given in EN 554, which may also be applied for small steam sterilizers.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 285:1996, *Sterilization — Steam sterilizers — Large sterilizers*.¹

EN 475, *Medical devices — Electrically-generated alarm signals*.

EN 866-3, *Biological systems for testing sterilizers and sterilization processes — Part 3: Particular systems for use in moist heat sterilizers*.

EN 867-1:1997, *Non-biological systems for use in sterilizers — Part 1: General requirements*.²

EN 867-5:2001, *Non-biological systems for use in sterilizers — Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*.

EN 868 (all parts), *Packaging materials and systems for medical devices which are to be sterilized*.³

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*.

EN 60529, *Degrees of protection provided by enclosures (IP code) (IEC 60529:1989)*.

¹ Currently under revision by CEN/TC 102.

² EN 867-1 is currently under revision by ISO/TC 198 and CEN/TC 102 (Vienna Agreement).

³ EN 868-1 is currently under revision by ISO/TC 198 and CEN/TC 102 (Vienna Agreement).

EN 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements (IEC 61010-1:2001)*.

EN 61010-2-041, *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes (IEC 61010-2-041:1996)*.⁴

EN 61326, *Electrical equipment for measurement, control and laboratory use — EMC requirements (IEC 61326:1997)*.

EN ISO 228-1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation (ISO 228-1:2000)*.

EN ISO 3746, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:1995)*.

EN ISO 4017, *Hexagon head screws — Product grades A and B (ISO 4017:1999)*.

EN ISO 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves (ISO 4126-1:2004)*.

EN ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)*.

EN ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2000)*.

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

NOTE Other definitions relevant to steam sterilization and its validation are given in EN 285 and EN 554.

3.1

absolute pressure

pressure for which the zero value is associated with absolute vacuum

[EN 764-1:2004, definition 4.5]

3.2

active drain of small steam sterilizers

drain through which fluids present in the chamber are discharged during the process

3.3

air removal

removal of air from the sterilizer chamber and sterilizer load sufficient to facilitate steam penetration

[EN 285:1996, definition 3.2]

3.4

automatic controller

device that, in response to pre-determined cycle variables, operates the sterilizer sequentially through the required stages of the cycle(s)

[EN 285:1996, definition 3.3]

⁴ Currently under revision by IEC/TC 66/WG 7.

3.5**biological indicator**

inoculated carrier contained within its primary pack ready for use

[EN 866-1:1997, definition 3.1]

3.6**calibration**

set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards

[VIM:1993, definition 6.11]

3.7**chamber temperature**

lowest temperature prevailing in the sterilizer chamber

[EN 554:1994, definition 3.3]

3.8**chemical indicator**

chemical indicator system in the form in which it is intended to be used

3.9**chemical indicator system**

combination of the chemical indicator reagent and its substrate

3.10**closed door**

door which is in the position required for it to be locked

3.11**cycle complete indication**

indication that the sterilization cycle has been satisfactorily completed as specified and that the sterilized load is ready for removal from the sterilizer chamber

3.12**cycle parameters**

specified physical properties, for example time, temperature and pressure, that influence the efficacy of the sterilization process

3.13**defined end-point**

visible change occurring after exposure to the specified variable(s) at a level equal to or greater than that specified for the indicator

[EN 867-1:1997, definition 3.2]

3.14**door**

lid or a similar device provided as a means of closing and sealing the sterilizer chamber

[EN 285:1996, definition 3.12]

3.15**double ended sterilizer**

sterilizer in which there is a door at each end of the sterilizer chamber

[EN 285:1996, definition 3.13]

3.16

equilibration time

period which elapses between the attainment of the sterilization temperature in the sterilizer chamber and the attainment of the sterilization temperature at all points within the load

[EN 554:1994, definition 3.5]

NOTE The sterilizer chamber temperature is usually called chamber temperature.

3.17

fault

recognition by the automatic controller that the pre-set cycle variables for the sterilization cycle have not been attained

[EN 285:1996, definition 3.17]

3.18

holding time of small steam sterilizers

period for which the temperature of all points within the usable space considering the temperature measurement reference position is held within the sterilization temperature band

NOTE The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

3.19

hollow load A

single ended open space where the ratio of length to diameter of the cavity is greater than or equal to 1 and less than/or equal to 750 ($1 \leq L/D \leq 750$) and where the length of the cavity is not greater than 1 500 mm ($L \leq 1\,500$ mm) or double ended open space where the ratio of length to diameter of the cavity is greater than/or equal to 2 and less than or equal to 1 500 ($2 \leq L/D \leq 1\,500$) and where the length of the cavity is not greater than 3 000 mm ($L \leq 3\,000$ mm) and which is not hollow load B

NOTE See annex A.

3.20

hollow load B

single ended open space where the ratio of length to diameter of the cavity is greater than or equal to 1 and less than/or equal to 5 ($1 \leq L/D \leq 5$) and where the diameter is greater than or equal to 5 mm ($D \geq 5$ mm) or double ended open space where the ratio of length to diameter of the cavity is greater than/or equal to 2 and less than/or equal to 10 ($2 \leq L/D \leq 10$) and where the diameter is greater than or equal to 5 mm ($D \geq 5$ mm)

NOTE See annex A.

3.21

inoculated carrier

carrier on which a defined number of test organisms has been deposited

[EN 866-1:1997, definition 3.8]

3.22

installation test

series of checks and tests performed after installation of the sterilizer in the place of use

[EN 554:1994, definition 3.9]

3.23

locked door

door with the locking device(s) fully engaged and where separate actions are required to unlock and open the door

3.24**maximum allowable pressure**

maximum pressure for which the equipment is designed

[EN 764-1:2004, definition 4.9]

NOTE 1 The maximum allowable pressure is specified by the manufacturer for a specific location. This is the location of connection of protective and/or limiting devices or the top of equipment or if not appropriate any other point specified.

NOTE 2 See Pressure Equipment Directive 97/23/EC, article 1, clause 2.3.

3.25**medical device**

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[EN ISO 13485:2003, definition 3.7].

3.26**monitoring**

function of a device or person to check the attainment of the pre-set cycle parameters essential to the efficacy of the operating cycle

3.27**operating pressure**

fluid pressure occurring during specified operating conditions

[EN 764:2004, definition 4.8]

NOTE For the purposes of steam sterilization operating pressure is specified for the plateau period of a sterilization cycle.

3.28**plateau period**

equilibration time plus the holding time

[EN 285:1996, definition 3.24]

3.29**porous**

ability of a material or configuration of material(s) to absorb fluids

3.30

pressure vessel

vessel describing the sterilizer chamber, jacket (if fitted), door(s) and components that are in permanent open connection with the sterilizer chamber

[EN 285:1996, definition 3.25]

3.31

process challenge device (PCD)

object which simulates the worst case of conditions for attainment of the specified sterilization conditions within the items to be sterilized

[EN 867-5:2001, definition 3.2]

NOTE The device is so constructed that a biological or non-biological indicator system can be placed within the device in the position which it is most difficult for the sterilizing agent to reach. The design of the process challenge device depends on the nature of the goods to be sterilized and the sterilization procedure.

3.32

hazard

potentially detrimental effect on persons or the surroundings arising directly from either the sterilizer or its load

3.33

saturated steam

water vapour at a temperature corresponding to the boiling point of the source liquid

[EN 554:1994, definition 3.20]

3.34

small steam sterilizer

steam sterilizer which is unable to accommodate a sterilization module and has a chamber volume not exceeding 60 litres

3.35

solid

product that is not made from porous material and which has no recesses or features which present a greater or equal challenge to steam penetration than hollow load B

3.36

sterile

condition of a medical device that is free from viable micro-organisms

[EN 556-1:2001, definition 3.4]

3.37

sterilization

process undertaken to render a sterilizer load sterile

[EN 285:1996, definition 3.31]

3.38

sterilization cycle

automatic sequence of operating stages performed in a sterilizer for the purpose of sterilization

[EN 285:1996, definition 3.32]

3.39

sterilization cycle type

classification of a sterilization process based on the performance of the cycle

NOTE 1 These categories are demonstrated by compliance with relevant tests listed in this standard

NOTE 2 This standard defines three sterilization cycle types: B, N and S. Other claims may be made, but should not make reference to the sterilization cycle type listed.

3.40

sterilization module

imaginary rectangular parallelepiped of dimensions 300 mm × 300 mm × 600 mm used to express the usable space of sterilizers

3.41

sterilization temperature

minimum temperature of the sterilization temperature band

[EN 554:1994, definition 3.24]

3.42

sterilization temperature band

range of temperatures expressed as the sterilization temperature and the maximum allowable temperature which may prevail throughout the load during the holding time

[EN 554:1994, definition 3.25]

NOTE These temperatures are usually stated in whole degrees Celsius.

3.43

sterilizer

apparatus designed to achieve sterilization

[EN 285:1996, definition 3.36]

3.44

sterilizer chamber

part of the sterilizer which receives the sterilizer load

[EN 554:1994, definition 3.27]

3.45

sterilizer load

goods that are to be sterilized simultaneously in the same sterilizer chamber

[EN 554:1994, definition 3.28]

3.46

temperature measurement reference position

position for temperature measurement as identified by the manufacturer to represent the conditions in the usable space

3.47

theoretical steam temperature

temperature of saturated steam expressed in Kelvin, calculated from the measured pressure, using the following equation:

$$T = A + B (\ln P + C)^{-1.5} \quad (1)$$

⁵ IRVINE TH.F., LILEY, P.E., Steam and Gas tables with computer equations. *Academic Press*, 1984.

where

T is the theoretical steam temperature in Kelvin;

P is the measured pressure in megapascals, time averaged to result in a time constant between 1 s and 2,5 s;

A is 42,677 6 K;

B is -3 892,70 K;

C is -9,486 54

3.48

type test

series of checks and tests for a particular design of sterilizer to demonstrate compliance with the requirements of this standard

3.49

unloading door

door in a double ended sterilizer through which the sterilized load is removed from the sterilizer chamber after a sterilization cycle

[EN 285:1996, definition 3.42]

3.50

usable space of small steam sterilizers

space inside the sterilizer chamber which is not restricted by fixed parts or the appropriate furniture as specified by the manufacturer of the sterilizer for the intended use and which is consequently available to accept the sterilizer load

3.51

validation

documented procedure for obtaining, recording and interpreting data required to show that a process will consistently comply with pre-determined specifications

[EN 554:1994, definition 3.29]

3.52

water charge

volume of the water in the vessel from which the steam for the sterilization cycle is generated

3.53

works test

series of tests performed at the manufacturer's works to demonstrate compliance of each sterilizer with its specification

[EN 285:1996, definition 3.44]

4 General technical requirements

4.1 Dimensions

The usable space shall be insufficient in size to accommodate a sterilization module.

4.2 Materials

The materials used for components in contact with steam, including instrumentation, shall:

- resist the attack of steam and condensate;
- not lead to deterioration of the quality of the steam;
- not release any substances in such quantities that they could constitute an environmental or health risk.

NOTE 1 EN 285:1996, annex A suggests materials and combinations of materials that are suitable for specified applications in the construction of steam sterilizers.

NOTE 2 Materials should be assessed in accordance with the principles of EN ISO 10993.

4.3 Design and construction

4.3.1 Doors and locking devices

4.3.1.1 The door shall be capable of being closed without being locked, so that it can be re-opened and closed before a sterilization cycle is initiated.

4.3.1.2 When fitted, the door seal shall permit ease of cleaning of the contact surfaces and seal replacement.

4.3.1.3 After cycle start it shall not be possible to open a sterilizer door before cycle complete is indicated, except through special intervention that will lead to a fault indication.

4.3.1.4 For double ended sterilizers it shall not be possible for more than one door to be open at a time, except for maintenance purposes.

4.3.1.5 For double ended sterilizers it shall not be possible to open the unloading door before cycle complete is indicated.

4.3.2 Test connection(s)

4.3.2.1 The sterilizer shall be equipped with at least one standard test connection.

4.3.2.2 The test connection(s) shall have a female pipe thread conforming to EN ISO 228-G¼ according to EN ISO 228-1.

4.3.2.3 The test connection(s) shall be at a point of easy access to the chamber. The test connection(s) shall be clearly marked.

4.3.2.4 The steam inlet or vacuum ports and pipelines shall not be used for test connections.

4.3.3 Air filter

4.3.3.1 The air admitted to return the sterilizer chamber to atmospheric pressure after a vacuum assisted drying stage shall be admitted through a filter.

NOTE Air filters should be constructed from material resistant to corrosion and biodegradation. The filter material should be supported in a manner which minimizes damage to it.

4.3.3.2 The filter unit shall be readily accessible.

4.3.3.3 The filter shall be protected from any influence that may impair its proper function.

4.3.3.4 The filter shall retain not less than 99,5 % of particles greater than 0,30 μm .

4.4 Instrumentation, indication and registration devices

4.4.1 General

All instruments and indicating devices specified in 4.4 shall be located where they can be viewed readily by the operator under normal operation of the sterilizer and their function shall be identified.

Unless otherwise specified in this standard, the required instruments and gauges shall be readable by normal or corrected vision from a distance of 1 m and with a minimum illumination of (215 ± 15) lx.

4.4.2 Instruments and indicators

4.4.2.1 General

Sterilizers shall be provided with the following instruments:

- a) sterilizer chamber temperature indicating instrument;
- b) sterilizer chamber pressure indicating instrument;
- c) jacket pressure indicating instrument (if the sterilizer is fitted with a pressurised jacket).

NOTE The instrumentation listed in this clause may be subjected to additional national and international regulations.

4.4.2.2 Sterilizer chamber temperature indicating instrument

The chamber temperature indicating instrument shall:

- a) be either digital or analogue;
- b) be graduated in degrees Celsius;
- c) have a scale which includes 75 °C to 150 °C;
- d) have an accuracy of better than ± 2 °C over the scale range 75 °C to 150 °C;
- e) for analogue instruments, be graduated in divisions not greater than 2 °C;
- f) for digital instruments, have a resolution better than 1 °C;
- g) be adjusted to an accuracy of $+ 0$ °C/ $-1,5$ °C at the sterilization temperature;
- h) when used for a control function, have a broken sensor protection that fails to safety;
- i) have an ambient temperature error compensation not exceeding 0,04 K/K over the scale range;
- j) have means of adjustment in situ by the use of a special tool, key or code without dismantling the instrument;
- k) have a response time $\tau_{0,9} < 5$ s when tested in water.

NOTE The adjustment should preferably be possible with the instrument in place while viewing the face of the instrument.

4.4.2.3 Sterilizer chamber pressure instrument

The sterilizer chamber pressure instrument shall:

- a) be either digital or analogue;
- b) be graduated in kilopascals or bars;
- c) when the sterilization cycle includes a vacuum phase, have a scale which includes the range 0 kPa and 1,3 times the maximum allowable pressure or –1 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value with a zero reading at absolute vacuum or ambient pressure respectively;
- d) when the sterilization cycle does not include a vacuum phase, have a scale which includes the range 100 kPa and 1,3 times the maximum allowable pressure or 0 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value;
- e) have an accuracy of better than or equal to ± 5 kPa (0,05 bar) over the scale range;
- f) for analogue instruments, be graduated in divisions not greater than 20 kPa (0,2 bar);
- g) for digital instruments, have a resolution of better than or equal to 2 kPa (0,02 bar);
- h) when used for a control function, have a broken sensor protection that fails to safety;
- i) have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range;
- j) when the sterilizer chamber pressure instrument is adjustable it shall require the use of a special tool, key or code.

NOTE 1 The adjustment should preferably be possible with the instrument in place while viewing the face of the instrument.

NOTE 2 When digital pressure indicators are used, an additional mechanically actuated indicator can be required for compliance with national pressure vessel regulations.

NOTE 3 Standards supporting the Pressure Equipment Directive 97/23/EC may contain different requirements for the scale range.

4.4.2.4 Jacket pressure indicating instrument (if the sterilizer is fitted with a pressurised jacket);

The jacket pressure indicating instrument shall:

- a) be either digital or analogue;
- b) be graduated in kilopascals or bars;
- c) have a scale which includes the range 100 kPa and 1,3 times the maximum allowable pressure, or 0 bar and 1,3 times the maximum allowable pressure, given as absolute pressure value;
- d) have an accuracy of better than or equal to ± 10 kPa (0,10 bar) over the scale range;
- e) for analogue instruments, be graduated in divisions not greater than 20 kPa (0,2 bar);
- f) for digital instruments, have a resolution of better than or equal to 10 kPa (0,10 bar);
- g) when used for a control function, have a broken sensor protection that fails to safety ;
- h) have an ambient temperature error compensation not exceeding 0,04 %/K over the scale range;

- i) when the jacket pressure indicating instrument is adjustable it shall require the use of a special tool, key or code.

NOTE 1 The adjustment should preferably be possible with the instrument in place while viewing the face of the instrument.

NOTE 2 When digital pressure indicators are used, an additional mechanically actuated indicator can be required for compliance with national pressure vessel regulations.

NOTE 3 Standards supporting the Pressure Equipment Directive 97/23/EC may contain different requirements for the scale range.

4.4.3 Indicating devices

4.4.3.1 Loading side of the sterilizer

In addition to the instruments identified in 4.4.2.1, the loading side of the sterilizer shall be provided with indicating devices visible from the operating position providing at least the following information:

- a) "door(s) locked";
- b) "in progress";
- c) "cycle complete";
- d) "fault";
- e) sterilization cycle selected and the type of cycle according to this standard;
- f) sterilization cycle counter (see 4.4.3.4).

The cycle complete indication shall be cancelled when the door-opening process has been initiated.

4.4.3.2 Double ended sterilizer

In addition to 4.4.3.1, the unloading side of a double ended sterilizer shall be provided with indicating devices visible from the operating position providing the following information:

- a) sterilizer chamber pressure;
- b) "doors locked";
- c) "in progress";
- d) "cycle complete";
- e) "fault".

The cycle complete indication shall be cancelled when the opening of the door has been initiated.

4.4.3.3 Acoustic signals

When fitted, active acoustic signals shall comply with EN 475. The acoustic signal shall be time limited to a maximum of 30 s and/or it shall be possible to interrupt it.

4.4.3.4 Cycle counter

The cycle counter shall:

- indicate the total number of all cycles started.

- be capable of displaying a minimum of four digits with each digit making a full count of 0 to 9.

The cycle counter shall not be capable of being reset or altered by the user or operator.

4.4.3.5 Air leak indication

If the sterilizer utilizes a vacuum stage for air removal, it shall be equipped with an automated air leakage rate test cycle. This test cycle will operate between two pressures, one of which shall be equal to or lower than the lowest pressure during air removal and steam penetration considering all available sterilization cycles. An air leakage rate signified by a pressure change greater than 0,13 kPa/min shall result in a fault indication.

4.4.4 Recorders and recordings

4.4.4.1 General

4.4.4.1.1 Sterilizers shall be fitted with either a recorder or a process evaluation system according to 4.4.5.

NOTE 1 If the sterilizer is fitted with a process evaluation system, a registration unit for documentation of its results should also be fitted.

Recorders can be either analogue or digital.

All data sampled during the sterilization cycle shall be represented in the record. The recorder shall produce a record which remains readable for a period of at least 12 months when stored under ambient conditions.

NOTE 2 National regulations may require a longer period or a permanent record.

Records shall be readable by normal or corrected vision from a distance of 250 mm. and with a minimum illumination of (215 ± 15) lx.

4.4.4.1.2 The following parameters shall be recorded or, alternatively, evaluated by a process evaluation system according to 4.4.5:

- pressure, independent from the process controller and the temperature signal taken from the process controller, or;
- temperature, independent from the process controller and the pressure signal taken from the process controller;
- time, independent from the process controller or automatically verified to another source.

If a process evaluation system is used it shall comply with 4.4.5.

4.4.4.1.3 Analogue systems to be considered independent shall be completely separate. Digital systems to be considered independent shall have separate sensors, amplifiers and AD converters.

NOTE If in addition a process evaluation system is used, independence is not necessary.

4.4.4.2 Recorders producing analogue records

4.4.4.2.1 General

Temperature and pressure shall be recorded on the same chart.

The pressure and the temperature graduations of the scales shall coincide.

4.4.4.2.2 Time scale

For recorders producing analogue records a time scale of not less than 4 mm/min shall be used.

If times are marked, units shall be either in seconds or minutes or multiples thereof.

Time periods up to 5 min shall have an accuracy of $\pm 2,5 \%$ or better and for periods above 5 min, of $\pm 1 \%$ or better.

4.4.4.2.3 Temperature

Temperature recorders producing analogue records shall:

- a) have a chart graduated in degrees Celsius;
- b) have a chart graduated in divisions not greater than 2 K;
- c) have a scale which includes the range 50 °C to 150 °C;
- d) have an accuracy of $\pm 1 \%$ or better over the scale range 50 °C to 150 °C;
- e) have a resolution of 1 K or better;
- f) have the means to be adjusted within ± 1 K at the sterilization temperature;
- g) sample each channel at least once every 2,5 s;
- h) print data from each channel at least once 2,5 s.

4.4.4.2.4 Pressure

Pressure recorders producing analogue records shall:

- a) have a chart graduated in kilopascals or bars;
- b) have a scale which includes 0 kPa to 400 kPa (–1 bar to 3 bar);
- c) indicate zero either at absolute vacuum or at ambient pressure respectively;
- d) have an accuracy of $\pm 1,6 \%$ or better over the scale range 0 kPa to 400 kPa (–1 bar to 3 bar);
- e) when the sterilization cycle does not include a vacuum phase, have a scale which includes 100 kPa to 400 kPa (0 bar to 3 bar);
- f) when the sterilization cycle does not include a vacuum phase, have an accuracy of $\pm 1,6 \%$ or better over the scale range 100 kPa to 400 kPa (0 bar to 3 bar);
- g) sample each channel at least once every 2,5 s;
- h) print data from each channel at least once every 2,5 s;
- i) have a chart with graduated divisions not greater than 20 kPa (0,2 bar);
- j) have a resolution of 5 kPa (0,05 bar) or better;
- k) be adjusted to an accuracy of ± 5 kPa ($\pm 0,05$ bar) or better at the operating pressure.

4.4.4.3 Recorders producing digital records

4.4.4.3.1 General

Not all data sampled to produce a digital record needs to be printed but, the minimum recording shall include at least the information according to Table 2 for the specimen sterilization cycle in Figure 1.

4.4.4.3.2 Temperature

Temperature recorders producing digital records shall:

- a) have alpha numeric characters;
- b) have data identified by text or symbols;
- c) have the data presented as text or figures;
- d) have a paper width which has a space for a minimum of 15 characters per line;
- e) have a range which includes 50 °C to 150 °C;
- f) have an accuracy of $\pm 1 \%$ or better over the range 50 °C to 150 °C;
- g) have the means to be adjusted within $\pm 1 \text{ K}$ at the sterilization temperature;
- h) have a resolution of 0,1 K or better;
- i) sample each channel at least once every 2,5 s.

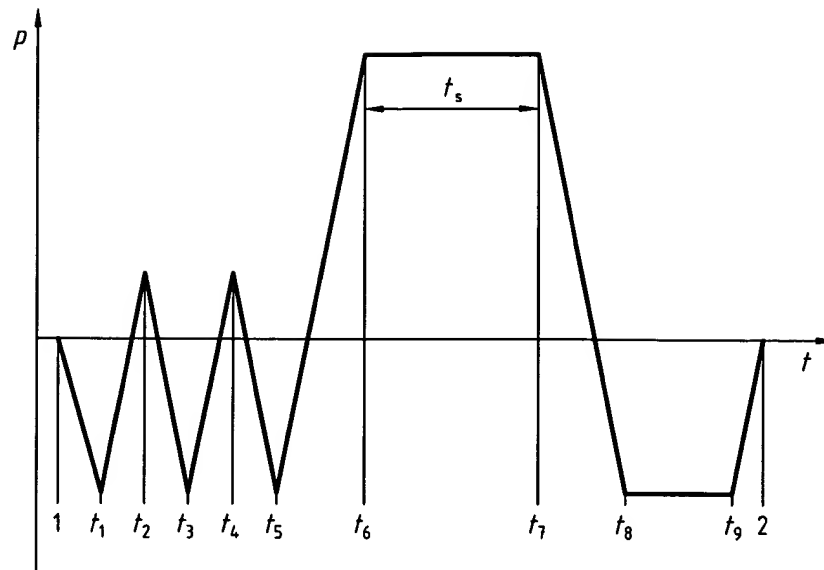
4.4.4.3.3 Pressure

Pressure recorders producing digital records shall:

- a) have alpha numeric characters;
- b) have data identified by text or symbols;
- c) have the data presented as text or figures;
- d) have a paper width which has a space for a minimum of 15 characters per line;
- e) have a range which includes 0 kPa to 400 kPa (–1 bar to 3 bar);
- f) when the sterilization cycle does not include a vacuum phase, have a scale which includes 100 kPa to 400 kPa (0 bar to 3 bar);
- g) have an accuracy of $\pm 1,6 \%$ or better over the range 0 kPa to 400 kPa (–1 bar to 3 bar);
- h) when the sterilization cycle does not include a vacuum phase, have an accuracy of $\pm 1,6 \%$ or better over the scale range 100 kPa to 400 kPa (0 bar to 3 bar);
- i) be adjusted to an accuracy of better than or equal to $\pm 5 \text{ kPa}$ ($\pm 0,05 \text{ bar}$) at the operating pressure;
- j) sample each channel at least once every 2,5 s;
- k) have a resolution of 1 kPa (10 mbar) or better.

Table 2 — Data and limiting values to be recorded

Programme step	Time	Temperature (measured value)	Pressure (measured value)	Sterilization programme ^c	Cycle No.	Date and sterilizer identification
START	X			X	X	X
$t_{1,3,5}$	X		x^b			
$t_{2,4}$	X		x^b			
t_6	X	X	X			
t_s	x^a	x^d	x^d			
t_7	X	X	X			
t_8	X		X			
t_9	X		X			
END	X					
$t_{1,3,5}$	time for vacuum pulse					
$t_{2,4}$	time for pressure pulse					
t_6	sterilization start time					
t_s	holding time					
t_7	sterilization end time					
t_8	drying start time					
t_9	drying end time					
^a	optional					
^b	maximum or minimum achieved					
^c	if the sterilizer is provided with different cycles					
^d	the highest and the lowest values of both, the pressure and the temperature prevailing during the holding time shall be printed unless these values are not evaluated by a process evaluation system according to 4.4.5					



Key

- 1 Start
- 2 End

Figure 1 — Diagram of a specimen sterilization cycle (given as an example only)

4.4.5 Process evaluation system

If fitted the process evaluation system shall:

- a) compare with a validated cycle any change in pressure and temperature and the period of the cycle during which the change occurs; any change beyond programmed limits shall cause a fault to be indicated;
- b) compare two independent temperature sensors, which may be those associated with the sterilizer chamber temperature indicating instrument and the temperature recorder; or
- c) be capable of comparing the theoretical steam temperature with the chamber temperature during the holding time;
- d) have a temperature measuring system accuracy better than or equal to that specified for the chamber temperature indicating instrument;
- e) have a pressure measuring system accuracy better than or equal to that specified for the chamber pressure indicating instrument;
- f) have a time measuring system with an accuracy of $\pm 1\%$ or better;
- g) operate to limits as specified by the manufacturer taking into account the process evaluation system accuracy;
- h) have been verified for its intended reaction upon specified process failures.

NOTE 1 See annex B for additional information on process evaluation systems.

NOTE 2 If a registration unit is fitted in addition to the process evaluation system, the following data should be registered: sterilizer identification, date, program, cycle number, process satisfactory or not satisfactory.

4.5 Control systems

4.5.1 Process control

4.5.1.1 The sterilization process can be either temperature or pressure controlled. In both cases the process control system shall ensure the presence of saturated steam.

4.5.1.2 The sterilizer shall be provided with an automatic controller. The automatic controller shall be programmed with the pre-set cycle parameters for each stage of the sterilization cycle. The pre-set cycle parameters shall only be adjustable by use of a special key, tool or code. The automatic controller shall be capable of monitoring the specified pre-set cycle parameters.

4.5.1.3 For a double ended sterilizer the controls used to start the sterilization cycle shall be located on the loading side of the sterilizer.

4.5.1.4 If the sterilizer is designed to retain water in the chamber after completion of the cycle, the visual indication "cycle complete" shall be activated only if the water will not boil at the moment of unsealing the door (see 4.4.3).

4.5.1.5 Means shall be provided for the operator to terminate the sterilization cycle without causing a hazard. When the sterilization cycle is terminated by the operator, a fault shall be indicated.

4.5.2 Performance verification

It shall be possible to assess the performance of an operating cycle:

- from readings noted from the sterilizer indicators and;
- from readings obtained from a recorder; or
- automatically by a process evaluation system.

4.5.3 Fault indication systems

4.5.3.1 The values for all cycle variables shall be specified by the manufacturer of the sterilizer. These shall include, but are not limited to, the switch points of all vacuum and steam pressure pulses, the sterilization pressure and temperature, and the holding times related to the available sterilization cycles (see 4.8.2).

NOTE A recorder can be used as part of a fault indication system.

4.5.3.2 When the values of cycle variables are outside the specified limits, or a failure of a service occurs which is sufficient to prevent the attainment of the values specified for the variables, the automatic controller shall:

- cause a visual indication that a fault has occurred;
- not cause a hazard.

NOTE 1 Visual indication of the stage of the sterilization cycle at which the fault occurred may be provided.

NOTE 2 In addition an audible alarm as described in 4.4.3.3. may be provided.

4.5.3.3 If the sterilizer is fitted with a printer for recording process parameters, the indication of a fault shall also be printed.

4.5.3.4 After a fault has been indicated, the automatic controller shall allow the sterilization cycle to be terminated without causing a hazard. To make the sterilizer ready for use again the use of a special tool, key or code shall be required.

4.5.3.5 A visual display of a fault shall continue at least until an action different from normal operation of the sterilizer is carried out to reset the system.

4.5.3.6 For double ended sterilizers, a fault shall be indicated at both ends and it shall not be possible to open the unloading door if a fault is indicated (see also 4.4.3.2).

4.6 Process

4.6.1 General

For moist heat sterilization using steam as the sterilant it is essential that all surfaces to be sterilized are subjected to saturated steam at a predetermined temperature for a predetermined period of time. Proper steam penetration into the load and — if applicable into the individual items — therefore is essential. Steam penetration requires adequate air removal. The requirements listed below and the associated test methods address factors and parameters that may promote or inhibit steam penetration and therefore the efficacy of the sterilization process.

4.6.2 Sterilization temperature, sterilization temperature band, holding time

The sterilization temperature, the sterilization temperature band and the holding time shall be pre-set and specified by the manufacturer and stated in the user instructions (see 4.8.2) for each available sterilization cycle.

4.6.3 Time-temperature relationships

The sterilizer shall provide sterilization conditions according to, or alternatives which can be proven to be equivalent to, the time temperature relationships given in Table 3.⁶⁾

Table 3 — Time-temperature relationships for sterilization conditions

Sterilization temperature °C	Minimum holding time min
121	15
126	10
134	3
143	1

4.6.4 Equilibration time

The equilibration time shall not exceed 15 s.

An equilibration time not exceeding 30 s is acceptable if:

- the rise of the theoretical steam temperature during the last 10 K of the heating stage is less than 8 K/min but greater than 1 K/min;
- during the last 10 K of the heating stage all temperatures measured in the chamber and the load as well as the theoretical steam temperature do not differ from one another by more than 2 K.

⁶ IMO, A new Approach to Sterilization Conditions, *Pharmaceutisch Weekblad Scientific Editie*, Vol 4, 1982.

4.7 Services and local environment

4.7.1 General

Sterilizers shall be designed to comply with the requirements of this standard when operated under the environmental conditions specified by the manufacturer.

NOTE The performance of a sterilizer is dependent on its design and construction, together with the quality of services and other conditions at its place of installation.

4.7.2 Electrical supply

The sterilizer shall be designed to operate when the mains supply voltage is maintained within $\pm 10\%$ of the nominal supply voltage.

4.7.3 Water supply for steam generation in the sterilizer

4.7.3.1 The sterilizer shall be designed to function with water free from contaminants in a concentration that could impair the sterilization process or harm the sterilizer or the sterilizer load.

NOTE Suggested maximum limits of some contaminants are given in annex C.

4.7.3.2 If a water reservoir is fitted:

- a) the reservoir and associated pipe work shall be fitted with a valve or other device to allow the reservoir to be drained by the operator or the automatic control system;
- b) the reservoir shall be large enough to contain sufficient water for the running of a complete sterilization cycle or the number of consecutive operating cycles specified by the manufacturer to be performed with the test load having the maximum steam consumption;
- c) the reservoir shall be vented and its design shall facilitate cleaning, inspection and filling;
- d) means shall be provided to indicate whether the water in the reservoir is sufficient for an operating cycle;
- e) the sterilizer shall not be capable of starting a cycle if there is insufficient water in the reservoir;
- f) the reservoir for feed water shall be designed to prevent back siphoning into the chamber.

4.7.4 Drains

The sterilizer shall be designed so that the temperature of water or vapour drained to an external drainage system does not exceed 100 °C.

NOTE The drain should be trapped and vented and not connected to other drains which can cause a back pressure or obstruction to flow.

4.7.5 Compressed air for control systems

When applicable the sterilizer shall be designed to operate with a compressed air supply, free of liquid water, filtered to 25 μm and free of oil droplets greater than 2 μm . The permissible air pressure range shall be stated by the manufacturer.

NOTE If compressed air is used for other purposes, additional requirements should be identified by the manufacturer.

4.7.6 Water used other than for steam generation

When water is used for cooling purposes and/or in a vacuum system the sterilizer shall be designed to be capable of operating with water which is of potable quality and supplied at a temperature in the range specified by the manufacturer, including 15 °C.

NOTE 1 The temperature of the water should be as low as possible because of the effect of temperature on the performance of the vacuum system. Higher water temperatures can modify the specified vacuum levels.

NOTE 2 The total hardness value of water should be between 0,7 mmol/l and 2,0 mmol/l. Hardness values outside these limits can cause scaling and corrosion problems.

NOTE 3 National regulations can require a backflow protection device to be fitted.

4.7.7 External steam supply to the sterilizer

The external steam supply to the sterilizers shall be in accordance with EN 285:1996, 13.3.

4.7.8 Electromagnetic compatibility

The immunity of the sterilizer to electromagnetic interference shall comply with EN 61326.

The emission of electromagnetic interference from the sterilizer shall comply with EN 61326.

4.8 Marking and accompanying documents

4.8.1 Pre-purchase information

The following information shall be provided to the purchaser prior to the purchase:

- a) Reference to this standard, if compliance with this standard is claimed.
- b) For all available sterilization cycles, the manufacturer shall identify the tests specified in this standard for which efficacy of the particular sterilization cycle is demonstrated through type testing. Results shall be listed or presented as a pass/fail table (see annex D). When alternative test methods are used, see 7.1.
- c) Quality information requirements.
- d) Installation information, including:
 - 1) the overall dimensions of the sterilizer;
 - 2) the overall mass of the sterilizer;
 - 3) the weight per support area (N/m^2) when the reservoir is filled with water and the chamber contains a maximum load;
 - 4) the weight per support area (N/m^2) when the reservoir is filled with water and the chamber or jacket is filled with water for a water pressure test, if such a test is required by pressure vessel regulations;
 - 5) the overall clearance required;
 - 6) the clearance required for the movement of the door(s).
- e) Type of electricity supply, DC or AC, single- or poly-phase voltage, current and frequency.
- f) For external steam supply, if applicable:
 - 1) the maximum and minimum supply pressure;

- 2) the maximum flow and usage rate.
- g) For water for steam generation in the sterilizer chamber, if applicable:
 - 1) the maximum and minimum pressure;
 - 2) the flow rate at minimum pressure;
 - 3) the maximum temperature;
 - 4) the volume used by the sterilization cycle having the highest steam consumption.

NOTE Suggested maximum limits of some contaminants are given in annex C.

- h) For compressed air, if applicable:
 - 1) the maximum and minimum supply pressure;
 - 2) the flow at minimum pressure;
 - 3) quality information/requirement.
- i) The maximum flow rate and temperature of any water drained and its maximum temperature.
- j) The total heat in Joules transmitted by the sterilizer to the surrounding air during an hour of continuous operation with the sterilization cycle giving the highest emission of heat, based on an ambient temperature of $(23 \pm 3) ^\circ\text{C}$.
- k) The mean and peak sound levels generated by the sterilizer, expressed as an A-weighted sound power level, when measured in accordance to EN ISO 3746.
- l) The manufacturer's recommended quality of the water used during the process.
- m) Dimensions of the usable space (see also 4.1).
- n) Allowed range for the ambient temperature, altitude, pressure and humidity, if applicable.

4.8.2 Manuals

4.8.2.1 General

When the sterilizer is delivered, the manufacturer shall provide the purchaser with at least the information in 4.8.2.2, 4.8.2.3 and 4.8.2.4.

4.8.2.2 User instructions

The user instructions shall include:

- a) loading, including maximum weight per item, loading weight per tray and/or basket and/or rack and maximum total weight;
- b) specification of the packaging materials which can be used in the sterilizer, with reference to EN 868;
- c) description of the controls and indicating devices;
- d) the minimum water charge in the water reservoir;
- e) the necessary frequency of draining the water reservoir, cleaning it and filling it with fresh water;

- f) specification of the water quality to be used;
- g) any actions in case of malfunction;
- h) description of the available sterilization cycles;
- i) the performance capabilities of each available sterilization cycle as described in annex D of this standard;
- j) description of safety devices;
- k) the dimensions of the usable space;
- l) the configuration of the load support system;
- m) the allowable range of ambient temperature, pressure, humidity, if applicable;
- n) a description of the operating cycle;
- o) the maximum temperature for each sterilization cycle option, including all phases of that cycle;
- p) the diagram of the pressure versus time relationship for the operating cycle(s);
- q) maximum total cycle time for the test loads as described in this standard.

NOTE The maximum total cycle time will normally be achieved when a cold sterilizer (non-preheated) is used.

- r) the time required for the sterilizer to be ready for routine use after the power is switched on.
- s) If the sterilizer is fitted with a recorder producing analogue records, a set of reference records of acceptable sterilization cycles, a list of the tolerances in pressure and temperature which are acceptable and instructions on how to read and interpret the records.
- t) If the sterilizer is fitted with a recorder producing digital records a list of the acceptable upper and lower limits of the measured and printed values for temperature, pressure and time and instructions on how to interpret the printed data.

When alternative test methods are used, see 7.1.

4.8.2.3 User maintenance

The user maintenance manual shall include:

- a) the maintenance interval or timetable;
- b) a complete list of spare parts replaceable by the user;
- c) a list of special tools necessary for user maintenance;
- d) procedure for each maintenance task;
- e) a list of technical service locations.

4.8.2.4 Technical maintenance, to be provided to the user on request

The technical maintenance manual shall include:

- a) maintenance interval or timetable;
- b) procedure for each maintenance task;

- c) specified cycle process switch points and limits for each setting fitted;
- d) electrical diagrams and circuits;
- e) the fluid plans and circuits;
- f) a complete list of spare parts;
- g) identification of non-user serviceable items;
- h) technical details on function and settings of safety devices;
- i) the setting of the air detector, if fitted;
- j) the positions of the highest and the lowest temperature in the chamber during empty chamber test.

4.8.3 Marking of the pressure vessel

The pressure vessel shall be marked according to EN 61010-2-041.

NOTE Pressure devices are regulated by the Pressure Equipment Directive 97/23/EC.

4.8.4 Marking of the sterilizer

4.8.4.1 The sterilizer shall be permanently and legibly marked with the following information, clearly visible from the operating position and using where appropriate, suitable standardised symbols (see e.g. EN 61010):

- a) identification of the function of the instruments and controls;
- b) if appropriate indication of the water quality to be used.

4.8.4.2 An identification plate that is clearly visible shall be affixed to the sterilizer frame or body and shall bear the following information:

- a) name and address of manufacturer and (if applicable) the legal entity responsible for introducing the product in the EU market;
- b) model/type identification;
- c) serial number;
- d) year of manufacture;
- e) rated voltage;
- f) current type;
- g) rated frequency;
- h) current or power consumption.

4.9 Accessories

The sterilizer shall be equipped with chamber furniture equivalent to the type used in the type test and suitable means to remove the load from the chamber.

NOTE Further guidance on accessories is given in annex E.

5 Performance requirements

5.1 General

A rationale for the tests is given in annex F.

5.2 Air leakage rate

If the sterilizer utilizes a vacuum stage for air removal in any sterilization cycle, the rate of air leakage into the sterilizer chamber during periods of vacuum shall not cause the rate of pressure rise to exceed 0,13 kPa/min (1,3 mbar/min) when tested in accordance with 10.2.

NOTE The limit set for this test is based on international experience with this test over many years (mainly with large, but also with small steam sterilizers). Although it can be argued that another limit should apply for smaller sterilizers, no alternative limits (possibly related to the chamber volume) have been demonstrated to be adequate. If and when such information is available this clause may require revision.

5.3 Attainment of the sterilization conditions

5.3.1 Attention is drawn to the statement, in the Introduction, of the necessity for validation of a sterilization procedure for a particular product.

5.3.2 For all loads except hollow load A, the presence of saturated steam in the usable space and the load is deemed to have been achieved when, throughout the holding time, all temperatures measured in the usable space and the load:

- are not lower than the sterilization temperature;
- are not more than 4 K above the sterilization temperature;
- do not differ from each other by more than 2 K.

The theoretical steam temperature which is calculated from the measured pressure shall also be considered as a measured temperature.

5.3.3 For hollow loads A and B only, the presence of saturated steam shall be demonstrated to be adequate by a satisfactory colour change in the chemical indicator system used, as specified by the indicator system manufacturer.

5.4 Product compatibility

5.4.1 Dynamic sterilizer chamber pressure test

The rate of pressure change during any part of the sterilization cycle shall not exceed 10 bar/min for any 2 s interval when tested in accordance with 10.3.

5.4.2 Maximum allowable temperature

The temperature in the usable space of the empty chamber shall not exceed the highest value of the temperature band when tested in accordance with 10.4.

5.5 Drying

5.5.1 For wrapped loads, any remaining moisture shall not lead to wet packages and shall not result in detrimental effects on the sterilizer load. Any remaining water droplets on the inner side of the film of laminate pouch shall evaporate within 5 min.

5.5.2 The change in moisture content of the load shall comply with 5.4.3 and 5.4.4 respectively when "cycle complete" is indicated.

5.5.3 For a solid load the moisture content shall not exceed 0,2 % when tested in accordance with 10.11.

5.5.4 For a porous load the moisture content shall not exceed 1,0 % when tested in accordance with 10.12.

5.6 Microbicidal efficacy

When microbiological tests are performed, as specified in 10.15, 10.16, 10.17, 10.18, 10.19 or 10.20, the sterilized biological indicator systems or the sterilized inoculated carrier shall not show growth. The reference biological indicators shall show growth.

5.7 Non-condensable gases

When a non-condensable gas test is performed, as described in 10.14, the percentage ratio of the volume of non-condensable gases to the volume of condensate collected shall be not greater than 3,5 %.

6 Safety

EN 61010-1, EN 61010-2-041 and EN 61326 shall apply.

For sterilizers excluded from Pressure Equipment Directive 97/23/EC, the safety devices, or their relevant components shall:

- a) be either fail-safe, have redundancy or be self diagnostic;
- b) be independent from other safety functions, unless the other safety functions are proven not to be affected by these safety devices or their relevant functions;
- c) have a protection level of at least IP 31 according to EN 60529;
- d) have safety valves complying with EN ISO 4126-1;
- e) have safety valves for steam and compressed air provided with means for manual testing, which shall be arranged such that the valves can be lifted off their seats when operating under pressure.

NOTE When the Pressure Equipment Directive 97/23/EC is not applicable, national regulations may apply.

7 Categories of tests

7.1 General

This standard gives the tests that shall be performed to demonstrate compliance with the performance requirements given in this standard.

The tests shall be performed with the relevant load support system in place. Specifications of the water used for steam generation and other facilities shall meet the specifications of the manufacturer of the sterilizer.

NOTE Annex F contains a rationale for the test method.

For particular sterilizer concepts and/or specified medical devices, some tests or test loads shall not be applicable for physical reasons. In such cases, alternative test procedures and/or specific test devices (e.g. PCD's) are necessary to demonstrate:

— compliance with the requirements given in 5.3.2 of this standard, or when this is not possible,

- achievement of a sterility assurance level (SAL) of 10^{-6} when tested according to EN ISO 14937.

In case of such tests being applied, these shall be fully documented. The following information shall be included in the manual or the pre-purchase documentation:

- the rationale for the standard test requirements not being applicable;
- the identification of the medical devices for which the cycle is being qualified;
- if used, a full specification of an alternative PCD to enable third parties to reproduce these tests and PCDs;
- the type test result on this specific item.

7.2 Type test

7.2.1 For each (available) sterilization cycle, the type tests specified in Table 4, for the relevant sterilization cycle type, including any additional tests which support the claims made by the manufacturer for the specific cycle, shall be performed. These tests shall be performed with one or more sterilizers manufactured according to the production specifications.

7.2.2 If the sterilizer is connected to external services during the type tests, these services shall comply with 4.7.

7.2.3 Sterilizers shall be considered to be of the same design and not require separate type testing if they have:

- a) the same number of doors in the same configuration;
- b) all service connections into the sterilizer chamber in the same orientation;
- c) the same control system with all sensors required in this standard located in the same positions and orientations;
- d) the same sterilization cycles.

7.2.4 The following design variations shall not require separate type testing:

- a) differences in the dimensions of the sterilizer chamber not greater than $\pm 10\%$ of the dimensions, with similar sterilizer chamber shapes;
- b) change of the plateau period within a sterilization cycle having the same sterilization temperature and the same air removal stage (see also 4.6.3);

NOTE A change in sterilization temperature may influence the air removal stage.

- c) any change of the design or sourcing of equipment, including chamber furniture, provided there is available documented evidence of validation of the design change to show that there is no adverse effect on the performance of the sterilizer which would affect compliance with this standard.

7.2.5 When sterilizer cycles are added or changed on an existing type tested sterilizer only these additional or changed cycles shall be type tested.

7.3 Works test

7.3.1 For each (available) sterilization cycle, the works tests specified in Table 4, for the relevant sterilization cycle type, including any additional tests which support the claims made by the manufacturer for the specific cycle, shall be performed.

NOTE The tests specified in Table 4 have not been established for special product programmes that are outside the scope of this standard.

7.3.2 The tests specified in Table 4 shall be performed with every sterilizer at the manufacturer's works. A works test is not required if an installation test is performed.

NOTE 1 Works or installation tests are the final tests before the sterilizer is released for use.

NOTE 2 The responsibility for the works test should be agreed between the supplier and the manufacturer of the sterilizer.

NOTE 3 Additional tests can be required by agreement between the manufacturer or supplier of the sterilizer and the purchaser.

7.3.3 If the sterilizer is connected to external services during the works test, these services shall comply with 4.7 of this standard.

7.4 Installation tests

7.4.1 If the sterilizer is assembled at the user site, or is connected to external facilities which may impair the sterilization process (power excluded), a full installation test as specified in Table 4 shall be performed.

7.4.2 If an installation test is performed, a works test is not required.

NOTE Works or installation tests are the final tests before the sterilizer is released for use.

7.4.3 If the sterilizer is connected to external services during the installation test, these services shall comply with 4.7 of this standard.

NOTE 1 The responsibility for the installation checks and tests should be agreed between the supplier and the user.

NOTE 2 Additional tests can be required by agreement between the manufacturer or supplier of the sterilizer and the purchaser.

8 Test equipment

8.1 General

Test equipment shall be capable of producing a record of all data obtained, to be retained for the interpretation of results. It shall be established that measuring equipment works within specifications at the time of use.

8.2 Temperature sensors

8.2.1 Temperature sensors shall be used to measure the temperature in locations specified in the tests described in this standard.

NOTE All temperature sensors used during a measurement should have the same performance specifications.

8.2.2 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature within the sterilization temperature band, known within $\pm 0,1$ °C, shall not differ by more than 0,5 K.

NOTE Temperature sensors can be either platinum resistance complying with type A of EN 60751 or thermocouple complying with one of the tables of tolerance type 1 of EN 60584-2.

8.2.3 The cross sectional area of any part of the sensor and its connecting wires within the sterilizer chamber shall not exceed 3,2 mm².

NOTE This is to avoid significant influence on the sterilization process or the steam penetration by the temperature sensors.

8.2.4 The accuracy of the temperature sensor shall not be affected either by its connection wires, or by the environment in which it is placed, e.g. pressure, steam or vacuum.

8.2.5 The temperature sensors shall have a response time of $\tau_{0,9} < 1$ s when tested in water.

8.3 Thermometric recording instrument

8.3.1 A thermometric recording instrument(s) shall be used in conjunction with temperature sensors to record the temperatures measured in the locations specified in the tests described in this standard. It can also be used to check thermometric instruments fitted to the sterilizer.

8.3.2 If more than one instrument is used, means shall be provided to synchronise time within an accuracy of 1 s.

8.3.3 The thermometric recording instrument shall be able to record from at least three channels for the works and installation tests and from at least eight channels for the type test. The channels can be multiplexed or independent of each other. The sampling rate for each channel shall be at least once per 2,5 s.

8.3.4 The scale range for analogue thermometric recording instruments shall include 50 °C to 150 °C. The minor mark interval shall not exceed 1 K, shall have a minimum width of 1 mm and the chart speed shall be not less than 15 mm/min. The resolution shall be equal to or less than 0,5 K.

8.3.5 Thermometric recording instruments, producing digital records shall register and record in increments of not more than 0,1 K and the scale range shall include 50 °C to 150 °C.

8.3.6 The error of the temperature measuring system (excluding temperature sensors) shall not exceed $\pm 0,25$ % when tested in an ambient temperature of (20 ± 3) °C. The additional error due to a change in the ambient temperature shall not exceed 0,04 K/K.

8.3.7 The temperature recording instrument shall be calibrated. Calibration and documentation shall be in accordance with the manufacturer's instructions. The calibration shall include a temperature within the sterilization temperature band. Calibration shall be carried out using a working or reference standard, which is traceable to a national standard or a primary standard.

8.3.8 The temperature measurement system shall be verified with an independent temperature reference source at a temperature within the sterilization temperature band at the place of use.

8.3.9 The temperature reference source shall meet the following requirements:

- it shall incorporate a reference standard thermometer which is traceable to a national standard or a primary standard and shall include the range 100 °C to 140 °C. The minor mark interval shall not exceed 0,2 K;
- it shall incorporate a pocket, sized to accommodate the temperature sensors as described in 8.2. The maximum temperature difference within the pocket shall not exceed 0,2 K and the control accuracy shall be to within $\pm 0,1$ K over the range of 100 °C to 140 °C.

8.4 Pressure measurement and recording instrument

8.4.1 A pressure measurement and recording instrument shall be used in conjunction with a pressure sensitive measuring element to record the pressure within the sterilizer chamber during a test sterilization cycle. It can also be used to check the pressure measuring instrument(s) fitted to the sterilizer.

8.4.2 A pressure recording instrument shall record the pressure measured by a pressure sensitive element(s). The sampling rate for each channel shall be at least once per second. The instrument can be integrated into the temperature recording instrument as an additional channel calibrated for pressure.

8.4.3 The scale range for recording instruments producing analogue records shall include 0 kPa to 400 kPa (0 bar absolute to 4 bar absolute). The minor mark interval shall not exceed 4 kPa (0,04 bar), have a minimum width of 1 mm and the chart speed shall be not less than 15 mm/min. The resolution shall be at least 2 kPa (0,02 bar).

8.4.4 Pressure recording instruments producing digital records shall register and record in increments of not more than 1 kPa (0,01 bar) and the scale range shall include 0 kPa to 400 kPa (0 bar absolute to 4 bar absolute).

8.4.5 During application the error from 0 kPa to 400 kPa (0 bar absolute to 4 bar absolute) in the indicator and measuring/recording system shall not exceed ± 2 kPa when measured in an ambient temperature of $(20 \pm 3) ^\circ\text{C}$.

8.4.6 The temperature coefficient of the measuring system shall not exceed 0,01 %/K at the temperature at which the pressure sensor is to be used.

8.4.7 The error due to a change in the environmental temperature shall not exceed 0,02 %/K.

8.4.8 The natural frequency of the pressure measuring instrument and connected tubing shall be not less than 10 Hz. The time constant (0 % to 63 %) for rising pressure shall not be greater than 0,04 s.

8.4.9 The pressure recording instrument shall be calibrated using a working or reference standard which is traceable to a national standard or a primary standard. Calibration and documentation shall be in accordance with the manufacturer's instructions. The calibration shall include the use of the minimum pressure which will occur in the air removal stage of any of the sterilization cycles -20 % and the maximum pressure that may occur in any of the sterilization cycles $+10$ %.

8.5 Test equipment for the performance of the air leakage test

8.5.1 Absolute pressure indicator

The absolute pressure indicator required for air leakage testing shall:

- a) be either digital or analogue;
- b) be graduated in kilopascals or millibars;
- c) have a scale which includes 0 kPa to 16 kPa (0 mbar to 160 mbar absolute);
- d) have an absolute accuracy of ± 2 kPa or better over the scale range 4 kPa to 20 kPa (40 mbar to 200 mbar absolute);
- e) have an accuracy of linearity of 1 % or better over the scale range 4 kPa to 20 kPa (40 mbar to 200 mbar absolute);
- f) for instruments with an analogue display be graduated in divisions not greater than 0,4 kPa (4 mbar) and with a scale displacement equal to or more than 1 mm/0,1 kPa (1 mm/mbar);
- g) have a resolution of 0,1 kPa (1 mbar) for digital instruments.

8.5.2 Absolute pressure indicator for the determination of the ambient atmospheric pressure

The absolute pressure indicator required to determine the ambient atmospheric pressure shall:

- a) be either digital or analogue;
- b) be graduated in kilopascals;
- c) have a scale which includes 80 kPa to 105 kPa (800 mbar to 1 050 mbar absolute);
- d) have an accuracy of 1 % or better over the scale range 94 kPa to 105 kPa (940 mbar to 1 050 mbar absolute);
- e) be graduated in divisions not greater than 0,4 kPa (4 mbar) and with the scale not greater than 0,1 kPa/mm (1 mbar/mm) for analogue instruments;
- f) have a resolution of 0,1 kPa (1 mbar) for instruments with digital display.

NOTE The pressure measurement and recording instrument specified in 8.4 may be used.

8.5.3 Stopwatch

The stopwatch used in the air leakage test shall have an error of not more than $\pm 0,5$ s over a period of 15 min.

8.6 Porous load

8.6.1 General

The porous load shall be:

- a) composed of plain cotton sheets, bleached to a good white and having an approximate size of 450 mm \times 300 mm. The number of threads per centimetre in the warp shall be 30 ± 6 and the number of threads per centimetre in the weft shall be 27 ± 5 . The mass per unit area shall be approximately 180 g/m²;
- b) washed when new and when soiled;
- c) not subjected to any fabric conditioning agent;
- d) dried and aired;
- e) stored for at least 1 h in an environment between 15 °C and 25 °C at a relative humidity of 30 % to 70 %.

NOTE 1 Test packs which are not used within 1 h of preparation can be stored in the work-room, providing the environmental conditions are maintained within the limits specified above.

NOTE 2 Test packs comprising different materials and of different sizes and weights can be used provided equivalence with the test pack specified above has been demonstrated.

NOTE 3 Fabric conditioning agents and or colouring dyes can affect the characteristics of the fabric and can contain volatiles which may contribute to the content of non-condensable gases in the sterilizer chamber.

8.6.2 Small porous load, single wrapped

8.6.2.1 General

The small porous load is used to represent a small load of textiles which can be processed in a sterilizer and shall be composed of sheets of textile according to 8.6.1. The number of sheets shall be determined on the basis of volume and dimensions of the test pack. Unless 8.6.2.2 or 8.6.2.3 apply the test pack shall fill (20 ± 5) % of the usable space. The sheets shall be folded to form a parallelepiped as close to a cubic shape as the usable space allows. In all cases the small porous load shall be wrapped in a single layer of packaging complying with the EN 868 series as recommended by the manufacturer of the sterilizer and used in the testing of the sterilizer.

8.6.2.2 Reduced test pack

8.6.2.2.1 If the sterilizer usable space has:

- a volume of more than 54 l and;
- a diameter of at least 35 cm and;
- the sterilizer furniture does not hinder the reception of the test pack,

the reduced test pack according to 8.6.2.2.2 to 8.6.2.2.6 shall be used.

8.6.2.2.2 The reduced test pack is used in a one module sterilizer to check that, at the levels at which the process variables are set, rapid and even penetration of steam into the pack is attained. It is used for the small load tests, air detector tests, load dryness test, textiles and can be used with other materials to form a full load. The reduced

test pack is a reusable item that may be used for testing continuously if the requirements in 8.6.2.2.4, 8.6.2.2.5, and 8.6.2.2.6 are met.

NOTE The environmental aspects regarding cleaning intervals as well as means for cleaning and conditioning should be considered.

8.6.2.2.3 The test pack shall be composed of plain cotton sheets, each sheet shall be bleached white and have an approximate size of 900 mm × 1 200 mm. The number of threads per centimetre in the warp shall be (30 ± 6) and the number of threads per centimetre in the weft shall be (27 ± 5) .

8.6.2.2.4 The sheets shall be washed when new and when soiled and shall not be subjected to any fabric conditioning agent.

NOTE Fabric conditioning agents and colouring dyes can affect the characteristics of the fabric and can contain volatiles which will contribute to the non-condensable gases in the sterilizer chamber.

8.6.2.2.5 The sheets shall be dried and then aired for at least 1 h in an environment between 15 °C and 25 °C, with a relative humidity of 30 % to 70 %.

NOTE If the environment in which the sheets are aired or stored is dryer than corresponding to 15 °C/70 % rh or 25 °C/30 % rh errors may occur due to exothermic re-hydration of the test pack in the sterilizer.

8.6.2.2.6 After airing, the sheets shall be folded to a nominal size of 220 mm x 300 mm and then stacked to a nominal height of 150 mm. After compressing by hand, the pack shall be wrapped in similar fabric and then secured with tape not exceeding 25 mm in width. The total weight of the pack shall be $(4,0 \pm 0,5)$ kg.

NOTE After multiple use, the sheets may become compressed and compliance with 8.6.2.2.6 will not be met.

8.6.2.3 Standard test pack according to EN 867-5

If the sterilizer usable space has:

- a volume of more than 10 l and;
- diameter of at least 18 cm and;
- the sterilizer furniture does not hinder the positioning of the test pack,

the standard test pack according to EN 867-5 shall be used.

8.6.3 Small porous load, double wrapped

8.6.3.1 The small porous load is used to represent a small load of textiles which can be processed in a sterilizer and shall be composed of sheets of textile according to 8.6.1. The number of sheets shall be determined on the basis of volume and dimensions of the test pack. Unless 8.6.3.2 or 8.6.3.3 apply the test pack shall fill (20 ± 5) % of the usable space. The sheets shall be folded to form a parallelepiped as close to a cubic shape as the usable space allows. In all cases the small porous load shall be wrapped in a double layer of packaging complying with the EN 868 series as recommended by the manufacturer of the sterilizer and used in the testing of the sterilizer.

8.6.3.2 If the sterilizer usable space has:

- a volume of more than 54 l and;
- a diameter of at least 35 cm and;
- the sterilizer furniture does not hinder the reception of the test pack,

the reduced test pack according to 8.6.2.2.2 to 8.6.2.2.6 shall be used.

8.6.3.3 If the sterilizer usable space has:

- a volume of more than 10 l and;
- diameter of at least 18 cm and;
- the sterilizer furniture does not hinder the reception of the test pack,

the standard test pack according to EN 867-5 shall be used.

8.6.4 Small porous items, single wrapped

The test load of small porous items shall consist of multiple items with a total volume of less than 0,5 l or 5 % of the usable space, whichever is smaller. The density of each individual item shall be equal to or less than 400 kg/m³. The test load shall be composed of sheets of textile according to 8.6.1. The porous items shall be combined in a single pack with packaging complying with the EN 868 series, as recommended by the manufacturer of the sterilizer.

8.6.5 Small porous items, double wrapped

The test load of small porous items shall consist of multiple items with a total volume of less than 0,5 l or 5 % of the usable space, whichever is smaller. The density of each individual item shall be equal to or less than 400 kg/m³. The test load shall be composed of sheets of textile according to 8.6.1. The porous items shall be combined in a double pack with packaging complying with the EN 868 series, as recommended by the manufacturer of the sterilizer.

8.6.6 Full porous load, single wrapped

Use the test pack as defined in 8.6.2. The test pack shall be wrapped in a single layer of packaging complying with the EN 868 series as recommended by the manufacturer of the sterilizer. Fill the remaining usable space with identical test packs or, when these will not fit, separate sheets of textile, to fill (95 ± 5) % of the usable space.

8.6.7 Full porous load, double wrapped

Use the test pack as defined in 8.6.3. Fill the remaining usable space with identical test packs or, when these will not fit, separate sheets of textile, to fill (95 ± 5) % of the usable space.

8.7 Solid load, unwrapped

The solid load shall be composed of metal bolts. The metal bolts shall:

- be austenitic stainless steel, according to EN 10088-1;
- be hexagon head bolts EN ISO 4017 – M12 × 100;
- be cleaned, degreased and dried before use.

A number of bolts shall be used which represent the maximum weight of unwrapped solid instruments which can be processed, as specified by the manufacturer of the sterilizer.

8.8 Solid load, single wrapped

The solid load shall be composed of metal bolts as defined in 8.7.

The total mass of the test load shall be the maximum load mass specified by the sterilizer manufacturer. The bolts shall be divided into groups and each group shall be wrapped in a single layer of packaging complying with the EN 868 series as recommended by the sterilizer manufacturer. The mass of each package shall be the maximum unit mass specified by the sterilizer manufacturer.

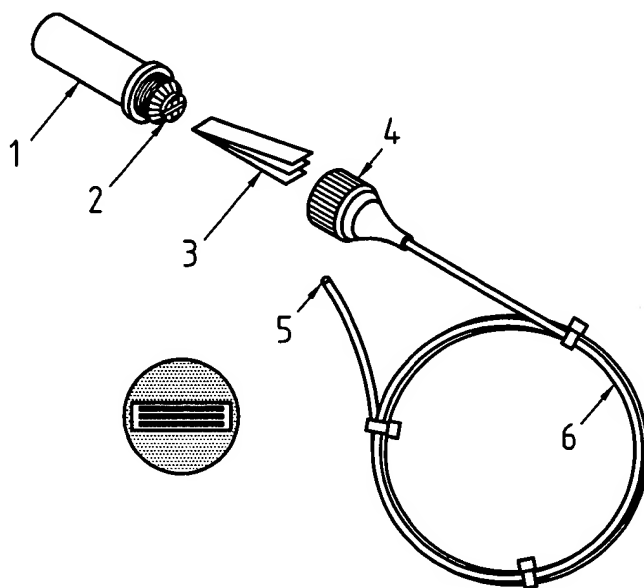
8.9 Solid load, double wrapped

The total mass of the test load shall be the maximum load mass specified by the sterilizer manufacturer. The bolts shall be divided into groups and each group shall be wrapped in a double layer of packaging complying with the EN 868 series as recommended by the sterilizer manufacturer. The mass of each package shall be the maximum unit mass specified by the sterilizer manufacturer.

8.10 Process challenge device and chemical indicator system for hollow loads A

The process challenge device for the hollow load A test shall comply with EN 867-5:2001, 4.5. An example of a process challenge device for hollow loads A is shown in Figure 2.

The chemical indicator system to be used in the process challenge device shall comply with EN 867-5:2001, 4.6.



Key

- 1 Capsule
- 2 Sealing
- 3 Indicator System
- 4 Connector
- 5 Open end
- 6 Tube

Figure 2 — Example of a process challenge device for hollow load A

8.11 Process challenge device and chemical indicator system for hollow load B

The hollow load B shall be composed of four high density polytetrafluoroethylene (PTFE) rigid plastic cylindrical test tubes which shall be capable of holding thermocouples or chemical indicators and shall have the following dimensions:

- a) single ended open:
 - internal diameter: 5 mm;
 - external diameter: 9 mm;
 - internal depth: 27,5 mm;

- external length: 33 mm;
- indicator dimensions: 27,5 mm × 6 mm × 0,7 mm.

b) double ended open:

- internal diameter: 5 mm;
- external diameter: 9 mm;
- external length: 55 mm;
- indicator dimensions: 55 mm × 6 mm × 0,7 mm.

c) single ended open:

- internal diameter: 10 mm;
- external diameter: 14 mm;
- internal depth: 55 mm;
- external length: 60 mm;
- indicator dimensions: 55 mm × 6 mm × 0,7 mm.

d) double ended open:

- internal diameter: 10 mm;
- external diameter: 14 mm;
- external length: 110 mm;
- indicator dimensions: 110 mm × 6 mm × 0,7 mm.

The receptacles shall be packed individually and shall be wrapped in packaging complying with the EN 868 series as recommended by the manufacturer of the sterilizer.

The chemical indicators used in this test shall be printed on a non-absorbing indicator carrier and shall comply with EN 867-1 and EN 867-5.

8.12 Balance for load dryness test

The balance used for the load dryness test shall be capable of weighing the test load with an accuracy of 0,1 g or better.

9 Test programme

The test programme shall include the tests listed in Table 4. For the rationale of the different tests see annex F.

Table 4 — Test programme

Test	Sterilization cycle type		
	B	S	N
Air Leakage	T, W/l ^b	T ^a , W/l ^b	T ^a , W/l ^b
Dynamic chamber	T	T ^c	
Empty chamber	T, W/l	T, W/l	T, W/l
Solid load, unwrapped		T ^f , W ^f	T, W
Solid load, single wrapped		T ^{d, f} , W ^{d, f}	
Solid load, double wrapped	T	T ^d , W ^d	
Hollow load A	T, W	T ^d , W ^d	
Hollow load B		T ^{d, e} , W ^{d, e}	
Small porous load, single wrapped		T ^{d, f} , W ^{d, f}	
Small porous load, double wrapped	T	T ^d , W ^d	
Full porous load, single wrapped		T ^{d, f, g} , W ^{d, f, g}	
Full porous load, double wrapped	T	T ^d , W ^d	
Small porous items, single wrapped		T ^{d, f} , W ^{d, f}	
Small porous items, double wrapped		T ^d , W ^d	
Dryness, solid load, unwrapped		T ^{d, f, g} , W ^{d, f, g}	
Dryness, solid load, single wrapped		T ^{d, f} , W ^{d, f}	
Dryness, solid load, double wrapped	T, W	T ^{d, f} , W ^{d, f}	
Dryness, full porous load, single wrapped		T ^{d, f} , W ^{d, f}	
Dryness, full porous load, double wrapped	T	T ^d , W ^d	
Dryness, small porous items, single wrapped		T ^{d, f} , W ^{d, f}	
Dryness, small porous items, double wrapped		T ^d , W ^d	
Residual air		T ^e	T
Additional tests ^{h, i}		T ^d , W ^d	
Dryness, small porous load, single wrapped		T ^{d, f, g} , W ^{d, f, g}	
Dryness, small porous load, double wrapped		T ^{d, g} , W ^{d, g}	
Microbiological tests ^j			

T: Type test W: Works test I: Installation test

^a if vacuum is used for air removal

^b if assembly on site is required

^c if the sterilization programme is designed for the sterilization of wrapped products

^d if claimed by the manufacturer

^e not if hollow A

^f not if double wrapped is claimed

^g not if dryness, solid load, double wrapped is claimed

^h Additional tests defined and performed by the manufacturer as part of his type testing procedure shall comply with 7.1.

ⁱ The test using a dedicated PCD (EN 867-5) representing the most critical challenge the manufacturer claims.

^j Optional microbiological tests for solid load, hollow load A, hollow load B, small porous load, full porous load and/or small porous items.

NOTE 1 If the manufacturer of the sterilizer is certified under a formal quality system, alternative testing may be substituted for the works/installation tests identified, provided that the manufacturer can demonstrate that the sterilizer performance is assured.

NOTE 2 The manufacturer may decide to perform some of the works tests at the point of installation (see 7.4.2).

NOTE 3 During testing, environmental aspects should be considered. By planning and performing the test programme in a logical sequence, the risk for unnecessary repetitions of tests due to the need for technical alterations of the sterilizer in a late stage of the test sequence can be minimized.

If in addition to technical testing optional microbiologically tests are performed, the requirements in 5.6 shall apply. These tests do not replace any other tests specified in this standard.

10 Test methods

10.1 General requirements on technical tests

10.1.1 General

The results of the tests shall be interpreted with regard to the specified cycle variables of the temperature band for the cycle type, including the reproducibility of the pressure profile.

NOTE See 4.5, 4.6 and 5.3.

The test data shall be retained as part of the type/works/installation test documentation.

10.1.2 Apparatus

The equipment shall comply with clause 8.

10.1.3 Type tests

For the thermometric measurements 8 temperature sensors shall be used. Any sensor connection cables shall be introduced into the sterilizer chamber through a test connection entry. The external pressure sensor shall be connected using a test connection. Type tests shall be repeated twice (three tests in all).

Unless it is specified by the manufacturer that the sterilizer may only be used after a heat up cycle, at least one of the type tests shall be performed with the sterilizer starting up at ambient temperature and another test shall be performed immediately after a heat up cycle.

If applicable, an air leakage test shall be carried out as specified in 10.2.

One temperature sensor shall be placed in the free chamber space and another next to the control temperature sensor. All other temperature sensors shall be distributed throughout the chamber and the load, as specified in the particular test method.

10.1.4 Works and installation tests, as applicable

For the thermometric measurements 3 temperature sensors shall be used. Any sensor connection cables shall be introduced into the sterilizer chamber through a test connection entry. The external pressure sensor shall be connected using a test connection.

If applicable, an air leakage test shall be carried out as specified in 10.2.

10.2 Air leakage test

10.2.1 Apparatus

Equipment according to 8.5 or equivalent (see 10.2.2).

10.2.2 Type test and works/installation test procedure

Carry out the test with the sterilizer at ambient temperature. For the test result to be valid the chamber temperature change in the period t_2 – t_3 shall not exceed ± 3 K.

NOTE 1 If the sterilizer cannot be run without preheating, the test can be carried out with a preheated sterilizer.

Connect the absolute pressure indicator to the sterilizer chamber with a means to protect it from the allowable working pressure of the sterilizing chamber if it is not designed to operate up to this pressure. Observe and record the ambient atmospheric pressure (p_0). Start the automated air leakage rate test cycle.

Observe and record the time (t_1) and the absolute pressure (p_1).

Wait for (300 ± 10) s after t_1 and then observe and record the absolute pressure in the chamber (p_2) and the time (t_2). The value of $(p_2 - p_1)$ shall not exceed $0,1 (p_0 - p_1)$.

NOTE 2 If the value of $(p_2 - p_1)$ exceeds $0,1 (p_0 - p_1)$ this could be due to the initial presence of excessive moisture in the sterilizer chamber.

After a further (600 ± 10) s again observe and record the absolute pressure in the sterilizer (p_3) and the time (t_3).

At the end of the test calculate the rate of pressure rise (kPa/min) for the 600 s period using the following equation:

$$\frac{\Delta p}{\Delta t} = \frac{p_3 - p_2}{10} \quad (2)$$

where

$\frac{\Delta p}{\Delta t}$ is the rate of pressure rise,

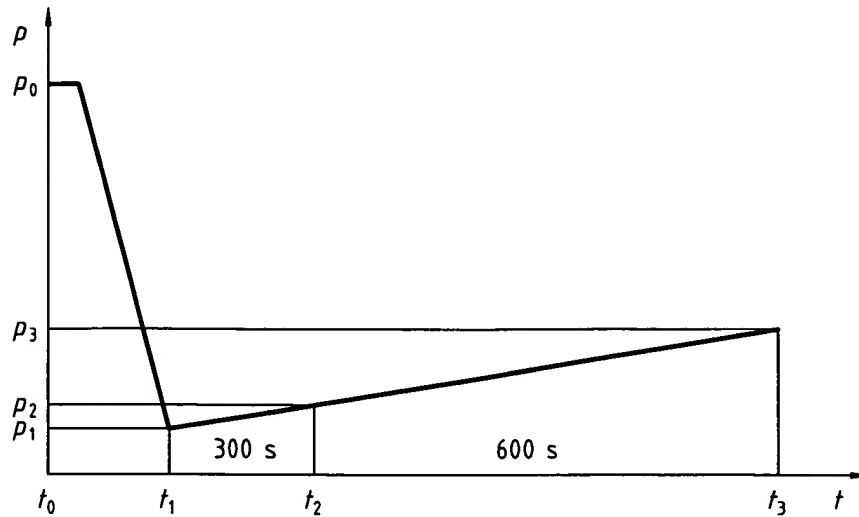
p_2 is the pressure after a period of 300 s,

p_3 is the pressure after a leakage time of 600 s.

Check for compliance with 5.2.

A different time interval may be used, provided that the accuracy and reproducibility is equal to or better than that obtained when using the equipment specified in 8.5.

NOTE 3 An example of a pressure curve is given in Figure 3.



Key

p_0	ambient atmospheric pressure	t_0	start of the test
p_1	lowest pressure level, which is equal to or lower than the level set for the cycle, during the air removal and steam penetration stage	t_1	time when the pressure level is reached
p_2	pressure after a period of 300 s	t_2	start of the leakage period
p_3	pressure after a leakage time of 600 s	t_3	end of the test

Figure 3 — Example of a pressure curve during the air leakage test

10.3 Dynamic sterilizer chamber pressure test

10.3.1 Apparatus

Equipment according to 8.4.

10.3.2 Type test procedure

Attach the pressure recording instrument to the test connection. Select the sterilization cycle with the standard drying time and in addition, when the sterilizer has a number of such sterilization cycles, select the cycle which gives the largest pressure decrease per time unit. Carry out a sterilization cycle with the sterilizer chamber empty. The pressures throughout the sterilization cycle shall be recorded.

At the completion of the test, proceed as follows:

- examine the records specified above for compliance with the cycle specification;
- check the pressure switch points for compliance with the intended process as specified by the manufacturer of the sterilizer;
- check for compliance with 5.4.1.

10.4 Empty chamber test

10.4.1 Apparatus

Equipment according to 8.2, 8.3 and 8.4.

10.4.2 Type test procedure

Connect the test equipment as specified in 10.1. Place a temperature sensor in the active drain and one at the location of the control sensor and at least six in the usable chamber space at locations which are shown to include the highest and the lowest temperature and which will demonstrate the chamber temperature profile and so indicate the chamber temperature variance. Measure the temperature of the water, if the sterilizer is designed to retain water in the chamber after completion of the cycle, during at least one of the cycles.

Check for compliance with 5.3 and 5.4.2.

10.4.3 Works/installation test procedure

Connect the test equipment as specified in 10.1. Distribute the temperature sensors throughout the usable space. Place the temperature sensors at the positions where the highest and lowest temperatures were indicated during the sterilization phase of the type test.

Check for compliance with 5.3 and 5.4.2.

10.5 Solid load test

10.5.1 Apparatus

Equipment according to 8.2, 8.3, 8.4 and either 8.7 (unwrapped) or 8.8 (single wrapped) or 8.9 (double wrapped).

10.5.2 Type and works/installation test procedures

Locate two temperature sensors at the positions where the highest and lowest temperatures were indicated during the empty chamber test. Fix the remaining temperature sensor in direct contact with a bolt using a single layer of autoclave tape with a width not exceeding 25 mm. This metal bolt shall be placed within the load. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

NOTE Depending on the type of temperature sensors, problems can occur when the metal of the sensor is in direct contact with stainless steel. Temperature sensors should be selected that will not give rise to electrochemical interference resulting from the direct contact of the sensor with the metal bolt. It is essential for the test that the temperature sensing bead is in thermal contact with the bolt.

10.6 Hollow load A test

10.6.1 Apparatus

Equipment according to 8.10.

10.6.2 Type test and works/installation test procedure

Allow the process challenge device to reach ambient temperature and make sure that the internal parts are dry before using it.

Carry out a sterilization cycle with the sterilizer chamber empty. Place the chemical indicator into the indicator holding device. Close and seal the capsule. Check that the plateau period does not exceed the endpoint of the

chemical indicator system (if necessary reduce the plateau period). Place the process challenge device into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. The sterilizer chamber shall be empty except for the sterilizer furniture. Immediately start the sterilization cycle. At the end of the sterilization cycle remove the process challenge device from the chamber. Remove the chemical indicator system from the indicator holding device.

Check for compliance with 5.3.3.

10.7 Hollow load B test

10.7.1 Thermometric test (optional for works and installation tests)

10.7.1.1 Apparatus

Equipment according to 8.11.

10.7.1.2 Type test procedure

Allow the receptacles to reach ambient temperature before using them and make sure that the internal parts are dry.

Connect the equipment as specified in 10.1. Distribute at least 6 temperature sensors throughout the usable chamber space. Locate four of these temperature sensors inside the receptacles and ensure that each receptacle includes one temperature sensor. For single ended open receptacles locate the temperature sensor at the bottom of the receptacle. For double ended open receptacles locate the temperature sensor in the middle of the receptacle. Ensure that there is no contact between the temperature sensitive part of the sensors and the receptacle. Turn the wires of the temperature sensors back at the inlet of the test receptacle and fix them by a piece of autoclave tape at the outside of the receptacle. Locate the two remaining temperature sensors at positions where the highest and lowest temperature were indicated during the empty chamber test. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.1.

10.7.1.3 Works/installation test procedure

Allow the receptacles to reach ambient temperature before using them and make sure that the internal parts are dry.

Connect the equipment as specified in 10.1. Distribute the temperature sensors throughout the usable space. Place one of these temperature sensors in the test receptacle shown to be the most critical during the type test. Locate another temperature sensor at the position shown to be the most critical during the empty chamber test. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.2.

10.7.2 Chemical indicator system test (works or installation tests only)

10.7.2.1 Apparatus

Equipment according to 8.11.

10.7.2.2 Works/installation test procedure

Allow the receptacles to reach ambient temperature before using them and make sure that the internal parts are dry.

Fit each test receptacle with a chemical indicator system. Check that the holding (plateau) time does not exceed the response time of the chemical indicator system. If necessary reduce the holding (plateau) time to be the end-point of the chemical indicator system. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. Remove the test receptacles from sterilization chamber at the end of the sterilization cycle. Remove the chemical indicator system from the test receptacle and check the colour with the specifications for the indicator as provided by the manufacturer of the indicator.

Check for compliance with 5.3.3.

10.8 Small porous load test

10.8.1 Apparatus

Equipment according to 8.2, 8.3, 8.4 and 8.6.2 (single wrapped) or 8.6.3 (double wrapped).

10.8.2 Type test procedure

Connect the equipment specified in 10.1. Distribute at least six temperature sensors throughout the usable chamber space. Place at least four of these temperature sensors in the test load as specified in Figure 4. Close and seal the packaging and ensure a full closure throughout the sterilization cycle. Locate the two remaining temperature sensors at the positions where the highest and lowest temperature were indicated during the empty chamber test. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

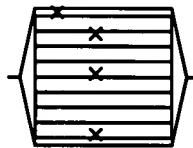


Figure 4 — Location of temperature sensors in the small porous load type test

10.8.3 Works/installation test procedure

Connect the equipment specified in 10.1. Distribute the temperature sensors throughout the usable chamber space. Place one of these temperature sensors in the test load as indicated in Figure 5. Locate the remaining temperature sensors at the positions with the highest and lowest temperature as identified during the empty chamber test. Close and seal the packaging and ensure a full closure throughout the sterilization cycle. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

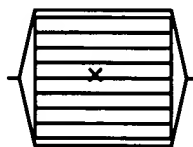


Figure 5 — Location of temperature sensors in the small porous load works/installation test

10.9 Full porous load test (single and double wrapped)

10.9.1 Apparatus

Equipment according to 8.2, 8.3, 8.4 and 8.6.6 (single wrapped) or 8.6.7 (double wrapped).

10.9.2 Type test procedure

Connect the equipment as specified in 10.1. Distribute at least six temperature sensors throughout the usable chamber space. Place at least four of these temperature sensors in the test load as indicated in Figure 6. Close and seal the packaging and ensure a full closure throughout the sterilization cycle. Locate the two remaining temperature sensors at the positions where the highest and lowest temperature were indicated during the empty chamber test. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

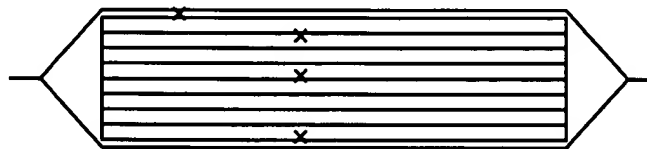


Figure 6 — Location of temperature sensors in the full porous load type test

10.9.3 Works/installation test procedure

Connect the equipment as specified in 10.1. Distribute the temperature sensors throughout the usable chamber space. Place one of these temperature sensors in the test load as indicated in Figure 7. Close and seal the packaging and ensure a full closure throughout the sterilization cycle. Locate the remaining temperature sensor(s) at the positions with the highest and lowest temperature as identified during the empty chamber test. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

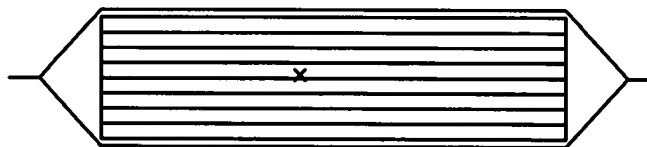


Figure 7 — Location of temperature sensors in the full porous load works/installation test

10.10 Small porous items test (single and double wrapped)

10.10.1 Apparatus

Equipment according to 8.2, 8.3, 8.4 and 8.6.4 (single wrapped) or 8.6.5 (double wrapped).

10.10.2 Type test procedure

Connect the equipment as specified in 10.1. Pre-heat the sterilizer by carrying out a sterilization cycle with the sterilizer chamber empty. Distribute at least six temperature sensors throughout the usable chamber space. Place at least four of these temperature sensors in the test load as indicated in Figure 8. Close and seal the packaging by a method that will ensure the package remains sealed throughout the sterilization cycle. Locate the two remaining temperature sensors at the positions where the highest and lowest temperature were indicated during the empty

chamber test. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

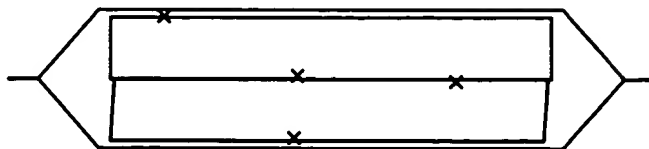


Figure 8 — Location of temperature sensors in the test load 'small porous items' type test

10.10.3 Works/installation test procedure

Connect the equipment as specified in 10.1. Distribute the temperature sensors throughout the usable chamber space. Locate one temperature sensor in the test load as indicated in Figure 9. Locate the remaining temperature sensor(s) in the positions shown to be most critical during the empty chamber test. Close and seal the packaging by a method that will ensure the package remains sealed throughout the sterilization cycle. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle.

Check for compliance with 5.3.

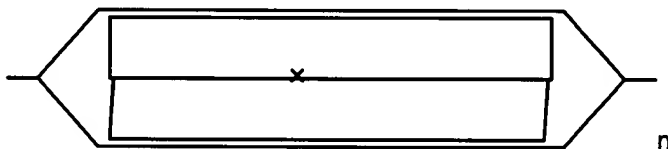


Figure 9 — Location of temperature sensors in the test load 'small porous items' works/installation test

10.11 Solid load dryness test

10.11.1 Apparatus

Equipment according to 8.5.3 and 8.12 with either 8.7 (unwrapped) or 8.8 (single wrapped) or 8.9 (double wrapped).

10.11.2 Type test procedure

Select the sterilization cycle to be tested. Weigh the test load including its packaging record its mass (m_1).

NOTE If the test load is supported by a removable tray it is recommended to weigh the test load including the tray.

Place the test load in the usable space supported by the chamber furniture in a position such that it will acquire the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle remove the test load from the sterilizer chamber. Weigh the test load within 2 min after the cycle complete indication. Record the mass (m_2).

Calculate the change in moisture content (C) using the following equation:

$$C = \frac{m_2 - m_1}{m_1} \times 100 \quad (3)$$

where

C is the change in moisture content, in per cent;

m_1 is the mass of the test load before sterilization, in grams;

m_2 is the mass of the test load after sterilization, in grams.

Check for compliance with 5.5.

10.11.3 Works/installation test procedure

Select the cycle to be tested and, if required, carry out a sterilization cycle with the sterilizer chamber empty. Place the test load in the usable space supported by the chamber furniture in a position such that it will acquire the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle remove the test load from the sterilizer chamber and visually inspect. In case of doubt, perform the test as specified for the type test.

Check for compliance with 5.5.

NOTE 1 This works test can be performed in combination with the works test according to 10.5.

NOTE 2 In laminate bags a slight misting on the inside of the laminate can occur due to the sudden temperature change when unloading the sterilizer.

10.12 Porous load dryness test (small and full, single and double wrapped)

10.12.1 Apparatus

Equipment according to 8.5.3, 8.12 and either 8.6.2 (small load single wrapped), 8.6.3 (small load double wrapped), 8.6.6 (full load single wrapped) or 8.6.7 (full load double wrapped).

10.12.2 Type test procedure

Select the sterilization cycle to be tested and carry out a sterilization cycle with the sterilizer chamber empty. Weigh the test load and record its mass (m_1). Place the test load in the usable space supported by the chamber furniture in a position such that it will acquire the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle remove the test load from the sterilizer chamber. Check the test load by visual inspection. No moisture spots shall be visible on the test load or the wrapping material. Weigh the test load within 2 min after the cycle complete indication. Record the mass (m_2). Calculate the change in moisture content using the equation (3).

Check for compliance with 5.5.

10.12.3 Works/installation test procedure

Select the cycle to be tested and carry out a sterilization cycle with the sterilizer chamber empty. Place the test load in the usable space supported by the chamber furniture in a position which will cause the maximum moisture. Immediately start the sterilization cycle. Upon completion of the sterilization cycle remove the test load from the sterilizer chamber. Check the test load by visual inspection. No moisture spots shall be visible on the test load or the wrapping material. In case of doubt, perform the test as specified for the type test.

Check for compliance with 5.5.

10.13 Small porous items dryness test (single and double wrapped)

10.13.1 Apparatus

Equipment according to 8.5.3, 8.12 and either 8.6.4 (single wrapped) or 8.6.5 (double wrapped).

10.13.2 Type test procedure

Carry out the test as specified in 10.12.2 for the porous load dryness test but using the test load for small porous items (8.6.4 or 8.6.5).

Check for compliance with 5.5.

10.13.3 Works/installation test procedure

Carry out the test as specified in 10.12.3 for the porous load dryness test but using the test load for small porous items (8.6.4 or 8.6.5).

Check for compliance with 5.5.

10.14 Non-condensable gases test

10.14.1 Apparatus

Equipment consisting of:

- a) 50 ml burette;
- b) 250 ml measuring cylinder;
- c) water condenser consisting of a tank capable of holding sufficient water to condense the steam from the sterilizer chamber without exceeding 75 °C at the end of the test, and with an overflow outlet which allows the excess water to be collected in the 250 ml measuring cylinder;
- d) a suitable bulkhead type fitting which can be accommodated by a suitable entry point either in the sterilizer door or chamber with the nozzle end of the fitting located inside the sterilizer chamber;

NOTE The fitting should have a bore no greater than 1 mm in diameter and be designed with a short nozzle which is capable of accommodating a short length of narrow bore rubber tubing. An example design of the fitting is shown in Figure 10.

- e) a control valve which can be fitted/connected to the bulkhead type fitting above, to both isolate the chamber from the external atmosphere and control the steam flow during the test.

10.14.2 Type test

Assemble the apparatus as illustrated in Figure 11. Fill the water condenser with sufficient cold water to prime the overflow pipe. Using a short length of small diameter silicon tube, fit a large syringe (25 ml or 50 ml) to the nozzle of the bulkhead fitting.

With the control valve open, prime the control valve, connecting tubing and the fitting with water by drawing air out of the capillary tube using the syringe.

NOTE 1 In order to remove as much air from the system as possible, continue to draw on the syringe as water is seen to issue from the capillary tube. Hold the syringe with the connection upper most, pull and push the syringe to help release any air bubble in the supply rubber tube or capillary tube.

Continue draw water into the syringe until no air bubbles are seen in the water issuing from the capillary tube. Shut off the control valve and remove the tubing and syringe from the fitting nozzle.

Top up the condenser with water. Using a short length of rubber tubing, connect the syringe to the burette tap and open the burette valve. Using the syringe, draw water into the burette until the water level reaches the zero mark on the burette. Close off the burette valve and remove the syringe and tubing. Top up the condenser with water until water flows from the overflow pipe. Wait for water to stop flowing from the overflow pipe and then place the 250 ml measuring cylinder under the condenser overflow pipe.

Record the temperature of the water in the condenser, close the sterilizer door and operate the cycle under test. Observe the sterilizer display and when the start of the holding period is reached note the chamber temperature and pressure. Then switch off the sterilizer electric supply.

NOTE 2 For completeness, the test may be repeated at different times during the plateau period of the sterilization cycle to verify the results.

Slowly open the control valve to allow the atmosphere in the sterilizer chamber to flow into the condenser water.

NOTE 3 Do not allow the flow to be too rapid as this will result in not all of the water vapour condensing or the escape of a fraction of the non-condensable gases. As steam is condensed in the cold water any gas present will not condense and be collected in the burette.

Continue to condense the chamber contents until the steam flow slows. At this point the control valve can be carefully opened fully to allow the final flow of steam to be condensed.

When the flow of steam from the sterilizer has stopped, turn off the control valve.

Record the volume of gas collected in the burette (V_b), the water temperature in the condenser and the volume of water collected in the measuring cylinder (V_c).

Calculate the ratio of the volume of non-condensable gases to the volume of condensed water collected and express as a percentage, using the following equation:

$$N = \frac{V_b}{V_c} \times 100 \quad (4)$$

where

N is the ratio of the volume of non-condensable gases to the volume of condensed water, in per cent;

V_b is the volume of non-condensable gases, in millilitres;

V_c is the total volume of condensed water collected, in millilitres.

Check for compliance with 5.7.

Dimensions in millimetres

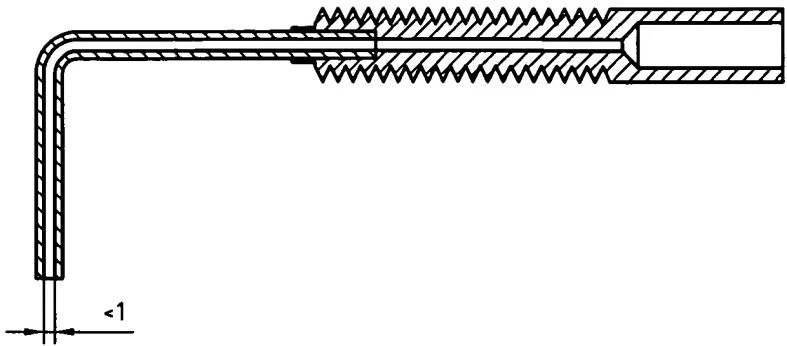
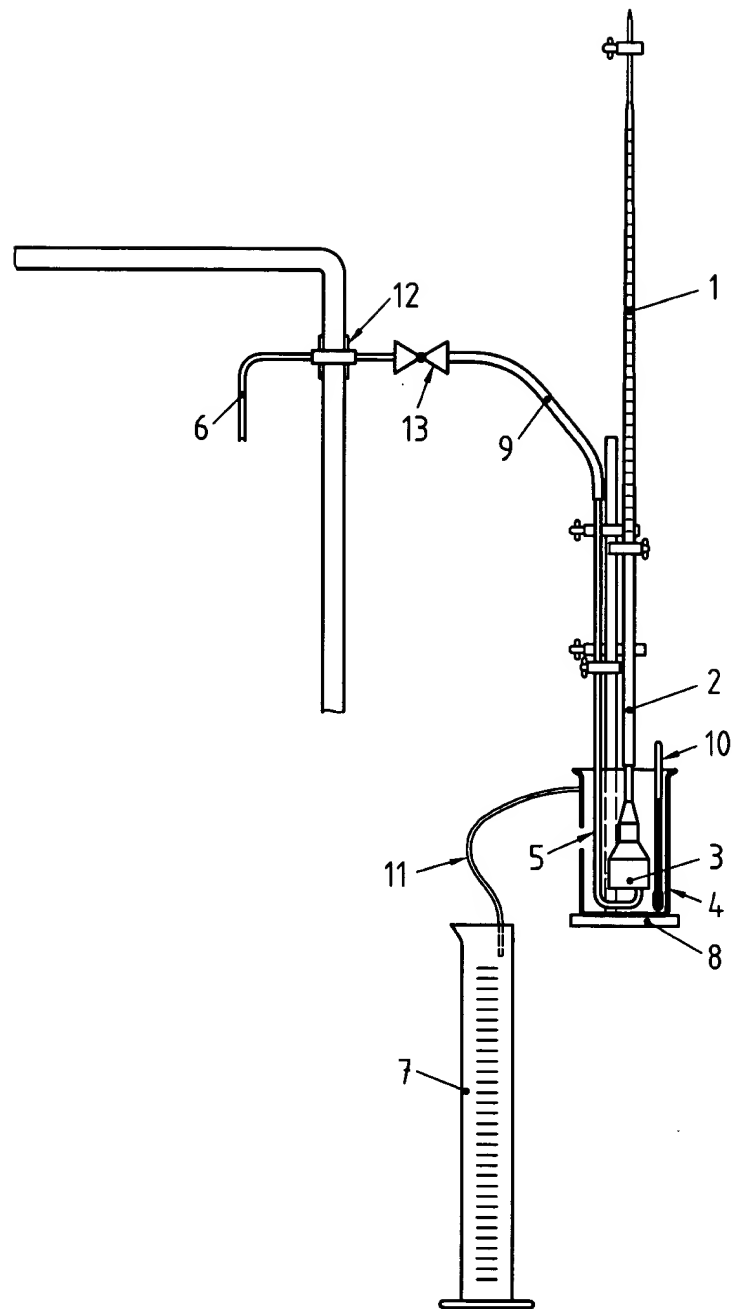


Figure 10 — Bulkhead fitting



Key

- | | | | |
|---|----------------------------|----|--------------------------------|
| 1 | 50 ml burette | 8 | Burette stand |
| 2 | Rubber tubing | 9 | Rubber tubing |
| 3 | Funnel with parallel sides | 10 | Temperature measurement system |
| 4 | 2 000 ml container | 11 | Overflow pipe |
| 5 | Steam sampling pipe | 12 | Coupling |
| 6 | Capillary sampling tube | 13 | Control valve |
| 7 | 250 ml measuring cylinder | | |

NOTE The exact position of the capillary tube inlet inside the sterilizer chamber is not specified as in practice, the collected gas volume has been found to vary depending on the capillary tube position in some sterilizers.

Figure 11 — Diagrammatic representation of the apparatus for the measurement of non-condensable gases

10.15 Microbiological test for solid loads

10.15.1 Apparatus

Equipment according to 8.7 (unwrapped) or 8.8 (single wrapped) or 8.9 (double wrapped).

At least five biological indicators complying with EN 866-3. An additional biological indicator is not processed and serves as a reference indicator positive control.

10.15.2 Type test and works/installation test procedure

Secure four biological indicators at the locations used for the temperature sensors in the load during the test according to 10.5. Close and seal the packaging by a method that will ensure it remains sealed throughout the sterilization cycle. Check that the plateau period does not exceed the specified exposure time of the biological indicator. If necessary, adjust the plateau period. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. After sterilization incubate the sterilized and the non-sterilized indicator according to EN 866-3.

After the incubation time, check for compliance with 5.6.

10.16 Microbiological test for hollow loads A

10.16.1 Apparatus

Equipment according to 8.10. Instead of the chemical indicator an inoculated carrier complying with EN 866-3 shall be used. The dimensions of the inoculated carrier shall be 36 mm × 6 mm × 0,7 mm. An identical inoculated carrier shall be used for the reference biological indicator and remains unprocessed.

10.16.2 Type test and works/installation test procedure

Carry out a sterilization cycle with the sterilizer chamber empty. Place the inoculated carrier into the indicator holding device. Close and seal the device. Wrap the device in a sheet of textile. Check that the plateau period time does not exceed the specified response time of the biological indicator. If necessary, adjust the plateau period. Place the process challenge device into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. At the end of the sterilization cycle remove the process challenge device from the chamber. Remove the inoculated carrier from the indicator holding device. Incubate the sterilized inoculated carrier and the non-sterilized indicator according to EN 866-3.

After the incubation time, check for compliance with 5.6.

Allow the process challenge device to cool to ambient temperature and make sure that the internal parts are dry before using it again.

10.17 Microbiological test for hollow load B

10.17.1 Apparatus

Equipment according to 8.11. Instead of the chemical indicator system an inoculated carrier complying with EN 866-3 shall be used. The dimensions of the inoculated carrier shall be 36 mm × 6 mm × 0,7 mm. An identical inoculated carrier shall be used as the reference biological indicator and remain unprocessed.

10.17.2 Type test and works/installation test procedure

Fit each test tube with a biological indicator. Position the inoculated carrier in the single ended open receptacles at the bottom of the tube. Locate the inoculated carrier in the double ended open receptacles in the middle of the tube. Check that the plateau period does not exceed the specified response time of the inoculated carrier. If necessary, adjust the plateau period. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. Remove the test tubes from the sterilization chamber at the end of the sterilization cycle. Remove the inoculated carriers from the test tubes. Incubate the sterilized inoculated carriers and the non-sterilized reference indicator according to EN 866-3.

After the incubation time, check for compliance with 5.6.

Allow the receptacles to cool to ambient temperature before using them again and make sure that the internal parts are dry.

10.18 Microbiological test for small porous loads

10.18.1 Apparatus

Equipment according to 8.6.2 (single wrapped) or 8.6.3 (double wrapped).

At least five biological indicators complying with EN 866-3.

10.18.2 Type test and works/installation test procedure

Secure four biological indicators at the locations used for the temperature sensors in the load during the test according to 10.8. Close and seal the packaging by a method that will ensure it remains sealed throughout the sterilization cycle. Check that the plateau period does not exceed the specified exposure of the biological indicator. If necessary, adjust the plateau period time. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. After sterilization incubate the sterilized indicators and the non-sterilized biological indicator according to EN 866-3. A fifth biological indicator is not processed and serves as a reference indicator positive control.

After the incubation time, check for compliance with 5.6.

10.19 Microbiological test for full porous loads

10.19.1 Apparatus

Equipment according to 8.6.6 (single wrapped) or 8.6.7 (double wrapped).

At least five biological indicators complying with EN 866-3.

10.19.2 Type test and works/installation test procedure

Secure four biological indicators at the locations used for the temperature sensors in the load during the test according to 10.9. Close and seal the packaging by a method that will ensure it remains sealed throughout the sterilization cycle. Check that the plateau period does not exceed the specified exposure time of the biological indicator. If necessary, adjust the plateau period. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. After sterilization incubate the sterilized indicators and the non-sterilized biological indicator according to EN 866-3. A fifth biological indicator is not processed and serves as a reference indicator positive control.

After the incubation time, check for compliance with 5.6.

10.20 Microbiological test for small porous items

10.20.1 Apparatus

Equipment according to 8.6.4 (single wrapped) or 8.6.5 (double wrapped).

At least five biological indicators complying with EN 866-3.

10.20.2 Type test and works/installation test procedure

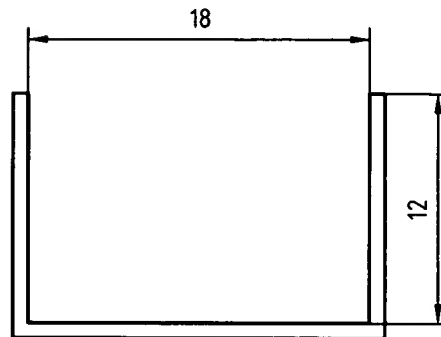
Secure four biological indicators at the locations used for the temperature sensors in the load during the test according to 10.10. Close and seal the packaging by a method that will ensure it remains sealed throughout the sterilization cycle. Check that the plateau period does not exceed the specified response time of the biological indicator. If necessary, adjust the plateau period. Place the load into the usable space according to the user instructions provided with the sterilizer, using the sterilizer furniture. Immediately start the sterilization cycle. After sterilization incubate the sterilized indicators and the non-sterilized indicator according to EN 866-3. A fifth biological indicator is not processed and serves as a reference indicator positive control.

After the incubation time, check for compliance with 5.6.

Annex A (informative)

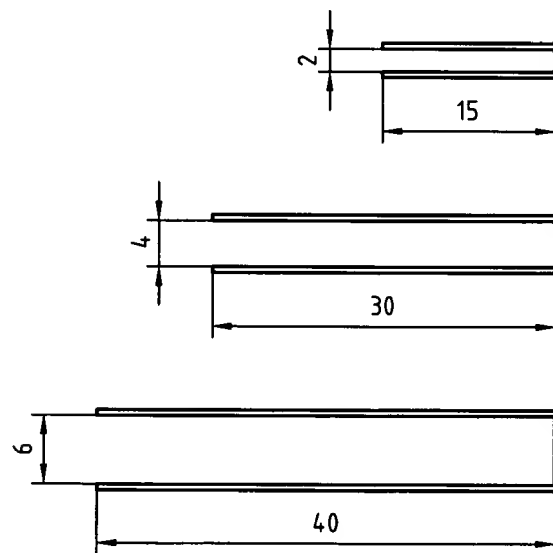
Clarification of the definition of hollow space A and hollow space B (see 3.19 and 3.20)

Dimensions in millimetres



NOTE The ratio of the length of cavity to diameter is less than 1.

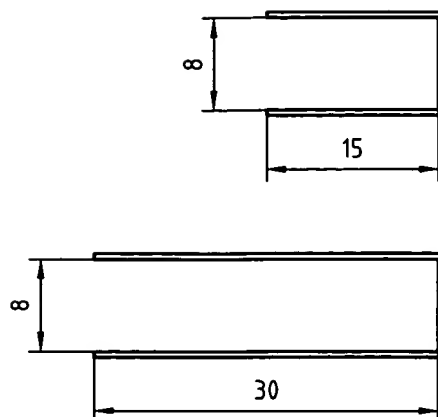
Figure A.1 — Object which is not hollow



NOTE The ratio of the length of cavity to diameter is greater than 1 and greater than 5 for all objects.

Figure A.2 — Hollow A objects

Dimensions in millimetres



NOTE The ratio of the length of cavity to diameter is greater than 1 and less than 5 for both objects.

Figure A.3 — Hollow B objects

Annex B (informative)

Process evaluation system

Usually a steam sterilization process is evaluated by interpreting the record of the physical parameters pressure, temperature and time. A well trained operator is able to assess the sterilization process and to decide whether or not the loads are sterilized and ready for use. Operators of small steam sterilizers are not always be able to interpret the sterilization process with the records of the physical parameters.

The application of a recorder on a small sterilizer should be considered if due interpretation by the operator can be expected or if a hard copy is required. As an alternative to a chart recorder, a process evaluation system can be considered. This system monitors the various factors essential to ensure sterilization and indicates to the operator if the cycle is acceptable or not.

Basically a process evaluation system should answer the same questions as the operator judging the records.

- Was the pressure(s) in the first vacuum and in all the pulses that followed low enough?
- Was the time taken to reach this pressure(s) within the limits?
- Was the pressure(s) in the first steam pulse and in all the pulses that followed high enough?
- Was the time taken to reach this pressure(s) within the limits?
- Was the pressure(s) during the holding time within the limits?
- Was the time taken to reach this pressure(s) within the limits?
- Was the temperature during the holding time within the limits?
- Were the temperatures, including the theoretical temperature, during the holding time within the limits?
- Was the holding time long enough?
- Was the drying pressure(s) low enough?
- Was the drying time long enough?

These questions should be answered with respect to the information given by the manufacturer according to 4.5.3.1 and 4.8.2.1.

Should any of these questions be answered with "no", the sterilization should be considered not satisfactory and a fault should be indicated. The load should be considered non-sterile.

Annex C (informative)

Suggested maximum limits of contaminants in and specification for water for steam sterilization

Table C.1 — Contaminants of condensate and feed water

	Feed water	Condensate
Evaporate residue	≤ 10 mg/l	≤ 1,0 mg/kg
Silicium oxide, SiO ₂	≤ 1 mg/l	≤ 0,1 mg/kg
Iron	≤ 0,2 mg/l	≤ 0,1 mg/kg
Cadmium	≤ 0,005 mg/l	≤ 0,005 mg/kg
Lead	≤ 0,05 mg/l	≤ 0,05 mg/kg
Rest of heavy metals, excluding iron, cadmium, lead	≤ 0,1 mg/l	≤ 0,1 mg/kg
Chloride	≤ 2 mg/l	≤ 0,1 mg/kg
Phosphate	≤ 0,5 mg/l	≤ 0,1 mg/kg
Conductivity (at 20 °C)	≤ 15 µs/cm	≤ 3 µs/cm
pH value	5 to 7,5	5 to 7
Appearance	colourless, clean, without sediment	colourless, clean, without sediment
Hardness	≤ 0,02 mmol/l	≤ 0,02 mmol/l
NOTE 1 The use of water for steam generation with contaminants at levels exceeding those given in this Table can greatly shorten the working life of a sterilizer and can invalidate the manufacturer's warranty of guarantee.		
NOTE 2 The condensate is produced from steam that has been taken from the empty sterilizer chamber.		

Compliance should be tested in accordance with acknowledged analytical methods.

Annex D (informative)

Example of a table to be supplied with pre-purchase documentation and with the instructions for use

The example covers a small sterilizer complying with this standard which provides five different process cycles, one for full porous loads and identified as a type B cycle in accordance with this standard, one for unwrapped solid instruments and identified as a type N cycle and three cycles identified as type S cycles, one for hollow instruments providing a level of drying but not sufficient for drying porous materials or wrappings, one for small porous items with a drying cycle capable of drying wrappings and one for specific medical devices which have been validated individually with the validation information being included in the documentation.

Table D.1 — Example

Type tests	Sterilization cycle type				
	B	N	S1	S2	S3
Dynamic sterilizer chamber pressure	X	X	X	X	X
Air Leakage	X		X	X	X
Empty chamber	X	X	X	X	X
Solid load	X	X	X	X	X
Small porous items	X				
Small porous loads	X				
Full porous load	X				
Hollow load B	X		X		
Hollow load A	X		X		
Multiple wrapping	X				
Dryness, solid load	X	X	X	X	
Dryness, porous load	X			X	
Residual air		X			
Specific medical devices (see manual)					X
X: in compliance with all applicable clauses of this standard					

Annex E **(informative)**

Load support systems

E.1 Sterilizers that have a horizontal chamber should be provided with load trays. The base of each tray and, if fitted, each lid should be perforated. Each tray should be self-supporting when withdrawn to one-half its length from the chamber.

E.2 Sterilizers that have a vertical chamber should be provided with load baskets. At least the horizontal surfaces of each basket should be perforated

E.3 Each load tray and/or basket should be fully removable, self draining and provided with means to keep its under-surface not less than 5 mm from a plane horizontal supporting surface.

E.4 The area of the perforations on each load tray and/or basket should be not less than 10 % of area of the perforated surfaces. The perforations should be uniformly distributed and should each have an area of not less than 20 mm².

E.5 The trays and/or baskets and the perforations should be so designed that, when placed in the sterilizer, they do not obstruct the drainage of the condensate from, or the penetration of steam into the trays and/or baskets.

Annex F

(informative)

Rationale for the tests

F.1 Air leakage test

The air leakage test is used to demonstrate that the quantity of air leakage into the sterilizer chamber during the periods of vacuum does not exceed a level which will inhibit the penetration of steam into the sterilizer load and will not be a potential cause of re-contamination of the sterilizer load during drying.

F.2 Dynamic sterilizer chamber pressure test

The dynamic sterilizer chamber pressure test is used to demonstrate that the rate of pressure change occurring in the sterilizer chamber during a sterilization cycle does not exceed a level which could cause damage to the packaging materials. This level is used as a performance requirement for materials complying with EN 868 series and has been chosen on the basis of a compromise between the needs of cost effective packaging and short, efficacious sterilization cycles.

F.3 Empty chamber test

The empty chamber test is performed to evaluate the sterilizer performance without the influence of a load. It allows the actual temperature and pressure settings to be verified against the intended settings.

F.4 Small porous load test

The small porous load test is used to demonstrate that, at the levels at which the controls are set, that steam will penetrate rapidly and evenly into the specified test pack.

F.5 Full porous load test

The full porous load test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained in the maximum density of porous load material which a sterilizer conforming to this standard is designed to process.

F.6 Solid load test

The solid load test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained throughout the load. The load shall comprise the maximum mass of solid instruments which a sterilizer conforming to this standard is designed to process.

F.7 Small porous items

The small porous items test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained in small porous items which a sterilizer conforming to this standard is designed to process.

F.8Hollow load A test

The hollow load A test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained in a process challenge device which conforms to the specification for hollow load type A which a sterilization cycle conforming to this standard is designed to process.

F.9Hollow load B test

The hollow load B test is used to demonstrate that, at the levels at which the controls are set, the required sterilizing conditions will be obtained in a process challenge device which conforms to the specification for hollow load type B which a sterilization cycle conforming to this standard is designed to process.

F.10Solid load dryness test

The solid load dryness test is performed with a reference sterilizer load and is used to demonstrate that the sterilization cycle is unlikely to cause moisture problems in routine production loads.

F.11Porous load dryness test

The porous load dryness test is used to demonstrate that the sterilization cycle without additional drying will not cause an increase in moisture in a porous load sufficient to inhibit the barrier properties of the packaging.

F.12Residual air test

The residual air test is used to determine the amount of residual air in the chamber.

F.13Microbiological test for small porous loads

The microbiological test for small porous loads is intended to show that when the controls are set at the levels at which compliance with the requirements for the small porous load has been demonstrated in the technical test, recovery of test organisms from the biological indicator placed in the test load cannot be achieved after the completion of a sterilization cycle.

F.14Microbiological test for full porous loads

The microbiological test for full porous loads is intended to show that, when the controls are set at the levels at which compliance with the requirements for the full porous load has been demonstrated in the technical test, recovery of test organisms from the biological indicator placed in the test load cannot be achieved after the completion of a sterilization cycle.

F.15Microbiological test for small porous items

The microbiological test for small porous items is intended to show that, when the controls are set at the levels at which compliance with the requirements for the small porous items has been demonstrated in the technical test, recovery of test organisms from the biological indicator placed in the test load cannot be achieved after the completion of a sterilization cycle.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clauses/sub-clauses of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 6	1	
4, 6	2	
4, 5, 10	3	
4, 5, 6	4	
	5	Not covered
6	6	
4, 5, 6	7	
4, 5	8	
4, 6	9	
	10	Not applicable
4, 6	11	
4, 6	12	
4	13	
	14	Not applicable
7, 8, 9, 10		In support of the cited requirements

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Bibliography

- [1] EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices.*
- [2] EN 554:1994, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat.*⁷
- [3] EN 764-1:2004, *Pressure equipment — Terminology — Part 1: Pressure, temperature, volume, nominal size.*
- [4] EN 866-1:1997, *Biological systems for testing sterilizers and sterilization processes — Part 1: General requirements.*⁸
- [5] EN 60073:2002, *Basic and safety principles for man-machine interface, marking and identification — Coding principles for indicators and actuators (IEC 60073:2002).*
- [6] EN 60584-2:1993, *Thermocouples — Part 2: Tolerances (IEC 60584-2:1982 + A1:1989).*
- [7] EN 60751:1995, *Industrial platinum resistance thermometer sensors (IEC 60751:1983 + A1:1986).*
- [8] EN ISO 10993 (all Parts), *Biological evaluation of medical devices.*
- [9] ISO/DIS 14538:1997, *Biological evaluation of medical devices — Establishment of permissible limits for sterilization and process residues using health-based risk assessment.*
- [10] EN ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004).*
- [11] 93/42/EEC, *COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.*
- [12] 97/23/EC, *Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment.*
- [13] IRVINE TH.F., LILEY, P.E., *Steam and Gas tables with computer equations. Academic Press, 1984*
- [14] IMO, *A new Approach to Sterilization Conditions, van Asten and Dorpema, Pharmaceutisch Weekblad Scientific Edition, Vol 4, 1982*
- [15] *International Vocabulary of Basic and General Terms in Metrology (VIM), 2nd edition, ISO, 1993.*

⁷ Currently under revision by ISO/TC 198 and CEN/TC 204 (Vienna Agreement).

⁸ Currently under revision by ISO/TC 198 and CEN/TC 102 (Vienna Agreement).

Nichols, Rose

From: Weinstein, Wendi
Sent: Friday, April 03, 2009 4:35 PM
To: Nichols, Rose
Subject: FW: AUTOKLAVKAMMARE - (your ref - 003300-794, our ref - 2016278) Response to OA - Please confirm safe receipt
Attachments: 20090403_AUTOKLAVKAMMARE (your ref - 003300-794 our ref - 2016278) Instructions for response to OA.doc; EN_13060_PUB_2004.pdf

Here are the instructions for the -794 6-month case due on Tuesday. The file is in my office, but if you could shell an Amendment that would be helpful.

Meant to tell you I'll be at the PTO most all day on Monday, 8-4pm or so.

From: Daniel Fritsche [mailto:Daniel.Fritsche@awapatent.com]
Sent: Fri 4/3/2009 5:01 AM
To: Weinstein, Wendi
Cc: Lisbeth Pfister
Subject: RE: AUTOKLAVKAMMARE - (your ref - 003300-794, our ref - 2016278) Response to OA - Please confirm safe receipt

Hi Wendi,

Please find slightly updated instructions and a standard document for "small sterilizers" attached. If at all possible, I would like to see the reply before you submit it to the USPTO.

Have a nice weekend!

Daniel

From: Weinstein, Wendi [mailto:wendi.weinstein@bipc.com]
Sent: den 2 april 2009 18:01
To: Daniel Fritsche
Subject: RE: AUTOKLAVKAMMARE - (your ref - 003300-794, our ref - 2016278) Response to OA - Please confirm safe receipt

Thank you Daniel for your instructions, and sorry that I missed your call earlier today.
Best regards,
Wendi

**Buchanan Ingersoll &
Rooney PC**
Wendi L. Weinstein, Esquire
Counsel

703 299-6872 direct 1737 King Street, Suite 500
703 836-2021fax Alexandria, VA 22314
wendi.weinstein@bipc.com

4/3/2009

From: Daniel Fritsche [mailto:Daniel.Fritsche@awapatent.com]
Sent: Thursday, April 02, 2009 11:58 AM
To: Weinstein, Wendi
Cc: Lisbeth Pfister
Subject: AUTOKLAVKAMMARE - (your ref - 003300-794, our ref - 2016278) Response to OA - Please confirm safe receipt
Importance: High

Dear Wendi,

Please find "draft" instructions attached. I will have to get back to you tomorrow with a reference to a suitable standard for steam sterilization in an autoclave device.

You can contact me at any time if you have comments or questions.

Best regards,

Daniel

Awapatent has been named Sweden IP Firm of the Year 2008 by the industry's leading global magazine, Managing Intellectual Property. The survey that forms the basis for this distinction is the largest of its kind in the industry today and is based on recommendations from more than 2,000 respondents. Read more here: <http://www.managingip.com/Default.aspx>

Daniel Fritsche, M.Sc., Eng. Phys.

European Patent Attorney

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4/3/2009

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